Exhibit 48

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

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IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	:	MDL NO. 2875
	:	CIVIL NO. 19-2875 (RBK/JS)
THIS DOCUMENT APPLIES TO ALL CASES	:	HON. ROBERT B. KUGLER

- CONFIDENTIAL INFORMATION -
SUBJECT TO PROTECTIVE ORDER

\- - -

April 5, 2021

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Videotaped remote deposition of ERIC GU, Ph.D., taken pursuant to notice, was held via Zoom Videoconference, beginning at 7:02 a.m., China Standard Time, on the above date, before Michelle L. Gray, a Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter, and Notary Public.

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VIDEOGRAPHER:
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Phil Hughes
(Check Interpreter)

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I N D E X

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E X H I B I T S

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EXHIBITS (Cont'd.)

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NO.	DESCRIPTION	PAGE
ZHP Gu-226	E-mail Thread 3/7/14 Subject, SynCores Presentation ZHP-01397314-15	54
ZHP Gu-227	Contract Assessment Table ZHP-00000215	101
ZHP Gu-228	Letter Re: Object: Submission of CAPA Plan to Joint Inspection ZHP 00493875-04	150
ZHP Gu-229	ICH Pharmaceutical Development Q8(R2) August 2009	253
ZHP Gu-230	ICH Quality Risk Management Q9 November 2005	254
ZHP Gu-231	Pharmaceutical Quality System Q10 June 2008	255

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EXHIBITS (Cont'd.)

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NO.	DESCRIPTION	PAGE
ZHP Gu-232	Final GMP Inspection Report ZHP 01862672-31	255

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PREVIOUSLY MARKED EXHIBITS

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NO.	DESCRIPTION	PAGE
ZHP-197	Tetrahedron N-dimethylformamide More than a Solvent	172
ZHP-199	R&D Report of Valsartan SC-1141 ZHP 00076653	119
ZHP-206	EMEA Guideline On the Limits of Genotoxic Impurities	89
ZHP-208	Guidance for Industry Genotoxic & Carcinogenic Impurities in Drug Substances	68

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NO.	DESCRIPTION	PAGE
ZHP-209	IARC Monographs On the Evaluation of the Carcinogenic Risk of Chemicals to Humans	64
ZHP-217	SYNCORES00037104-91	140

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DEPOSITION SUPPORT INDEX

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Direction to Witness Not to Answer
PAGE LINE
None.

Request for Production of Documents
PAGE LINE
None.

Stipulations
PAGE LINE
None.

Questions Marked
PAGE LINE
None.

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THE VIDEOGRAPHER: We are now on the record. My name is Judy Diaz. I'm a legal videographer from Golkow Litigation Services.

Today's date is April 5, 2021, and the time right now is 7:02 a.m.

This remote video deposition is being held in the matter of Valsartan, Losartan, and Irbesartan Products Liability Litigation MDL.

The deponent is Dr. Eric Gu, Ph.D.

All parties to this deposition are appearing remotely and have agreed to the witness being sworn in remotely.

All counsel will be noted on the stenographic record.

The court reporter is Michelle Gray and will now swear in the witness.

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... ERIC GU, Ph.D., having been first duly affirmed/sworn, was examined and testified as follows:

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EXAMINATION

- - -

BY MR. SLATER:

Q. Dr. Gu, hello.

A. Hello.

Q. My name is Adam Slater. I'm going to take your deposition for the next two days.

A. Okay.

Q. You understand that's what we're here for?

A. Yes.

Q. Have you ever had your deposition taken before?

A. No.

Q. It's important that you understand a few things and that we

confirm a few things before we start. Okay?

A. Okay.

Q. First of all, you understand that you're now under oath and must tell the truth?

A. Yes, I do.

Q. Okay, great. We would appreciate direct, accurate, responsive information in response to our questions that will allow us to go through this more quickly and more efficiently. Okay?

A. Okay.

Q. If I ask you a question that doesn't make sense to you for some reason -- I may mispronounce a term, I may ask a question -- or I just don't ask a question in an artful way based on the scientific issue, or whatever it may be.

If for any reason I ask you a question that you don't understand and don't think that you can testify in response to both truthfully and completely, just tell me, and you'll tell

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me what's unclear, and we'll try to rephrase the question. Okay?
A. Okay, sure.
Q. Attorneys will talk during a deposition and make objections at times. That's normal. I would just ask that you allow the objection to be discussed and then I would think in most cases you'd go ahead and answer the question. But that's for your counsel to decide. Okay?
A. Okay.
Q. Did you have the opportunity to prepare for this deposition?
A. Yes, I have.
Q. Can you tell me what you did to prepare for the deposition?
A. Reviewed some documents and I talked to my counsels.
Q. Do you know how much time you spent preparing for the deposition?
A. I didn't count, you know, exactly how many times. But let's see. A few sessions with my counsels and reviewed some documents. Spent about,

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let's say -- I don't know, 20, 40 hours.
Q. 20 to 40 hours?
A. No, I just -- rough numbers. I didn't count. I didn't -- you know --
Q. I'm just repeating what -- I'm just repeating what you said to make sure that I heard you correctly. Did you say 20 to 40 hours is your estimate?
A. No. Take that away. I didn't count. I don't know. If you are talking about reading documents, I just reading from time to time.
Q. You said that you met -- or rephrase.
You said that you spoke to your counsel. Which attorney or attorneys did you speak to in preparation for the deposition?
A. Rick, Patrick, and I think Nathan, yeah.
Q. Mason, you said?
A. Nathan. N-A-T-H-A-N, yeah.
Q. Nathan. Got it. Any other attorneys that you spoke to?

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A. Nope.
Q. How many times did you speak with any one or more of those attorneys that you listed?
A. I think about four or five times.
Q. When was the first time you spoke to them to prepare?
A. That was about, let's see, a month ago, you know. We schedule a meeting that's every -- usually Tuesday night, China times.
Q. How long would each meeting take? Was it the same amount of time each time? Was it different? Can you tell me, please?
A. It could be different. Sometimes take, let's say, a couple hours, sometimes one and a half, you know.
Q. So one and a half to two hours each time?
A. That's about right. Yeah. I remember there the one meeting maybe

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last about three hours or so.
Q. Did any of your meetings with your attorneys to prepare for this deposition last more than three hours?
A. Let me think. More than three hours? No, I don't recall.
Q. What if any documents did you review in preparation for the deposition?
A. You know, I wasn't with the company until 2014, so I, you know, find all those documents, research report and risk assessment and those documents relate to my -- to my -- you know, to my job.
Q. Okay. You said a research report. Which research report?
A. The process, you know, developed back in 2011 or so.
Q. Are you talking about the process development research report from SynCores?
A. Yes, you are right.
Q. When you said risk

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assessment, what risk assessment were you referring to?
A. That was I would say after 2018, June, and we did some of the, you know, how else, you know, toxic impurity was formed, the investigation, the research assessment -- the risk assessment, you know, to see where the GTI formed, how we going to -- how we can remove that.
Q. Are you talking about after in June of 2018 the NDMA and the NDEA was discovered and SynCores was asked to try to help develop an optimized process to prevent the formation of those impurities?
A. Yes and no. That was out of 2018, June, when we discovered NDMA and NDEA.
The first thing we did was to, you know -- doing the laboratory research to find out how this was formed in the process and how -- that's first -- that's one thing.

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Second thing is -- no, let me backwards. Okay.
To develop a method how we are going to detect the NDMA first. Then we see how we can remove that from the process. The entire risk assessment research in the laboratory.
Q. Any other documents that you reviewed?
A. Let me remember. The -- also the 483, and the response to the 483 and some of the, you know, raw data that relates to the research report.
Q. I'm sorry. I missed the last thing that you said.
A. The data for the research report.
Q. The data for the --
A. From other ones -- yeah, yeah.
Q. The data for which research report?
A. You know, for the risk assessment report.

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Q. In -- that was performed in 2018?
A. Yeah, that was performed at 2018. I recall that's maybe -- yeah, 2018. The exactly month, I don't remember. It's probably July or August or afterwards.
Q. Were you involved in that risk assessment?
A. Yeah, I was involved, you know, of course, the allocation, the walkthroughs, and review the reports.
Q. One second. I'm having a little computer issue here. I've got to fix it.
A. Okay.
Q. Stay on the record. Don't worry.
A. All right.
Q. Any other documents that you can recall reviewing in preparation for the deposition?
A. You know, yes. Other documents such as the, you know, SOPs and

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these type of document.
Q. You said SOPs and what else?
A. I reviewed many documents. User log, there's reports, SOPs, and 483 document, and those documents. That's pretty much it.
MR. SLATER: Cheryll, I don't know what exhibit we're on, but maybe you can say it when you put it up. But let's put up the deposition notice, please.
MS. CALDERON: Sure. It's 223, is the next exhibit.
(Document marked for identification as Exhibit ZHP-223.)
BY MR. SLATER:
Q. All right. Have you seen this document?
A. Let's see. No. No.
Q. Did you search for any documents that may be produced to us tonight as part of your deposition?
A. Search what document?

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Q. Any of your personal documents that may relate to this case, did you search to see if you had any that had not been previously collected so they can be provided tonight?
A. As far as I understand, all the document has been provided to you.
Q. Yeah, my question is this: In connection with this deposition, did you search to see if any relevant documents to this litigation had not previously been produced so they could be produced to us in connection with the deposition.
A. That's a good question. How would I know? Okay. I don't know. What are you talking about?
Q. Did you make any effort to identify documents that were not previously produced to us as part of this litigation?
A. The answer is no.
Q. Do you keep handwritten notes in connection with your work?

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A. Not always. But sometimes I do.
Q. Any handwritten note --
MR. BALL: If you give me an opportunity to object. I'd appreciate it. Sorry.
BY MR. SLATER:
Q. Any handwritten notes that you may have created with regard to valsartan, do you know if those were produced to us?
A. You know what, valsartan, hand writing notes, no, I don't have it. I don't have any -- a lot of hand notes.
Q. Do you have any handwritten notes that you ever created in connection with your work on valsartan?
A. Okay. Let me be clear. I don't make hand notes, you know, for this valsartan, you know, case.
Q. How about during your work on the optimized process for valsartan? Did you create any notes in connection with that?

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A. No. Usually I just order -- you know, plan the research work. I don't make any notes.
Q. Did you type any notes in connection with the valsartan project?
A. I type some e-mails, but not notes.
Q. So in the production of documents, we should be able to find e-mails that you sent with regard to the valsartan optimized process?
A. Could you repeat the question again?
Q. Sure. Did you send e-mails in connection with your work on the valsartan project in 2018?
A. Do I produce e-mails regarding to the valsartan project? Is that what you're saying?
Q. Did you type any e-mails and send any e-mails in connection with the valsartan project in 2018?
A. I don't recall. That was 2018. But I do participate in the

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project.
Q. Would you expect that in your custodial folder of your e-mails, we should find e-mails with regard to the valsartan project, e-mails both from you and to you?
A. I don't know. Maybe.
Q. When you said maybe, that gives me pause, so I have to ask you. In your preparation for this deposition, did you review any e-mails that you either sent or received about the valsartan project in 2018?
A. I didn't review my e-mails. I don't have such habits. I only review the documents.
Q. In your work at SynCores, do you use more than one computer?
A. I have one computers.
Q. You've used one computer the whole time you've been there?
A. I used more than one computer. Let's say, one computer broke down, it was stolen, I replaced another

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one. Yeah, any given time, I had one computers.
Q. Did you say that your computer broke or did you say it was stolen or both? I thought you said --
A. I recall I lost, let's say, one computer when I travel. One computer was broken down and it crashed.
Q. When did you lose a computer when you traveled?
A. That's a good question. Let's see. Let me try and remember that. That was maybe in 2016 or so when I travel from San Francisco back to Shanghai. I lost my computer one time, yeah.
Q. When was that?
A. I just left on the airplane. And I find out, you know, I didn't have my computer. I call the airline. They said they didn't find it, so...
Q. When?
A. I don't remember exactly the time. I thought maybe it was 2016 time

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frame.
Q. Was the information on that computer backed up somewhere so that the data or information on the computer was not lost?
A. The computer, you know, was, you know, backed up from time to time. But I'm not sure 100 percent, maybe lost some data.
Q. Was there ever a point where you lost the computer where you realized something that you needed couldn't be found because it was on that computer?
A. I didn't think so, because it didn't impact my work.
Q. You said another computer -- well, let me ask you this.
The computer that you lost when you were traveling, was that a laptop?
A. Laptop.
Q. What type of laptop?
A. Gee, that was -- I remember, what was that? That was -- I think it

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was ThinkPad because I used a few brands. One is Acer. One is the ThinkPad. One is -- I used a Dell in the past. I think it was a ThinkPad.
Q. And you said that you had a computer that broke and crashed. Was that a different computer?
A. I think that was a Acer. A-C-E-R. You know that brand there.
Q. A-C-R?
A. A-C-E-R, Acer.
Q. When did that happen?
A. That was 2017 or '18, some time there. I don't keep notes of that. I'm sorry. That was -- I just give you rough timeline.
Q. When you said it broke and crashed, did you turn it back into the company? Was it a company computer?
A. Yeah, I turned it back to company. They tried to fix it, but they failed.
Q. Do you know what happened to the data and information that was on the

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computer?
A. I'm sorry. It's lost.
Q. Was any of the data that was lost when the computer broke relevant to the valsartan project in 2018?
A. I don't think so. Because the computer was backed up from time to time. If it was lost, lost less than, let's say, you know, a few weeks of data, okay.
Q. Since that time when that computer broke and crashed, have you used the same computer up till now?
A. I think so, yeah.
Q. What type of computer is that?
A. It's a ThinkPad.
Q. Do you have that computer with you?
A. In the room, in my bedroom.
Q. The computer that you're using for the deposition is what type of computer?
A. It's a Lenovo X390.

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Q. Was that provided to you by -- well, rephrase.
Who provided that computer to you?
A. The company computer.
Q. Which company provided that to you?
A. ZHP.
Q. Do you consider yourself to work for ZHP?
A. Yes. And I work for SynCores, but ZHP is the majority holder of SynCores.
MR. SLATER: Cheryll, let's go to Exhibit A of the deposition notice, please.
BY MR. SLATER:
Q. Have you seen that page or those lists of topics before right now?
A. Could you expand a little bit, please?
Q. Have you ever seen that document in front of you, Exhibit A listing 30(b)(6) topics? Have you seen

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that before?
MR. BALL: I think he asked if she can expand it, Adam.
MR. SLATER: Oh, expand it. I thought he said if I could explain it.
MR. BALL: No, expand it.
MR. SLATER: Are you able to make it bigger, Cheryll? Great.
BY MR. SLATER:
Q. Does that help you, sir?
A. Yes, that help. Yes, I saw these two items. Yes, I saw this from somewhere, maybe talking to my counsel sometimes, yeah.
Q. So I'll just ask again. This page, Exhibit A, have you seen the page before?
A. Yes.
Q. And did you review the topics listed and prepare yourself to testify on those topics?
A. Yes, exactly.
MR. SLATER: Let's go to the

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next page, please, Cheryll, this document.
BY MR. SLATER:
Q. We asked for your most recent curriculum vitae or LinkedIn profile. We were provided a document we're going to go through shortly. I just want to ask, do you have a LinkedIn profile?
A. I haven't, you know, been used LinkedIn -- I just, you know -- I haven't used LinkedIn for a while.
Q. But do you have a LinkedIn profile?
A. I used LinkedIn long time ago. I don't know anything about LinkedIn profiles.
Q. You know what LinkedIn is, right?
A. I know that's -- you know, connecting people looking for a job, you know, hiring people, you know, website.
Q. If I wanted to find -- rephrase.

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If I researched for you on LinkedIn, would I find a profile for you?
A. I'm sure you can. You can try. I think I'm on LinkedIn.
Q. Do you go on LinkedIn from time to time?
A. Not very often. The last time I used LinkedIn is about a couple months ago maybe, or whenever I got a message for anything.
MR. SLATER: Okay. Cheryll, we can take this document down and put up his CV as Exhibit 224 when you get a chance. Perfect.
(Document marked for identification as Exhibit ZHP-224.)
BY MR. SLATER:
Q. We've put a document up on the screen as Exhibit 224.
Can you tell me what that is, please?
A. That's my CV.
Q. Is it up to date?

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A. Yeah.
Q. Is it -- rephrase.
Is this CV accurate?
A. Yes.
Q. Let's go to the section under professional experience. It says Shanghai SynCores Technology Inc. Limited, February 2014 to the present.
A. Mm-hmm.
Q. Is that accurate?
A. Yes.
Q. This says your title is general manager. Is that your current title?
A. Hold on -- okay. It's the same.
Q. This has your title as general manager. Is that correct?
A. Correct.
Q. And is your current title general manager?
A. Yes.
Q. Have you held any other titles at Shanghai SynCores?

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A. No, that's the only title I have. In China we call it general manager, but manager as president of the company. So basically, I think that's the same.
Q. Are you the president of the company?
A. Yes.
Q. Have you been the president of Shanghai SynCores since February 2014?
A. Yes.
Q. When was the first time that you ever had any involvement with valsartan?
A. The first time was -- let me think. The first time I was involved in the valsartan, you know, project, that was -- that was -- that was after 2018, June, okay, when we -- you know, when we had a notice. About July time frame, I got a notice from the ZHP.
Q. Well, let's be clear. When was the first time that you had involvement with valsartan. Was it in

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July of 2018?
A. Yes, after July -- after June of the 2018.
Q. Well, I want to be clear. When you say your first involvement with valsartan was after June of 2018, are you saying that first involvement was in July of 2018?
A. If I remember correct, you know, when you are talking about when I was involved in the valsartan project, yes. It was after June of 2018.
Q. When did you first learn that valsartan was contaminated with NDMA and NDEA?
A. Like I just said, that was after June of 2018.
Q. After June of '18?
A. Yeah.
Q. So you didn't hear anything about the NDMA impurity in valsartan in June of 2018? That's not something that you heard about at all during that month?
A. You just confused me. Would

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you repeat the question again?
Q. Sure. Did you learn in June 2018 that valsartan was contaminated with NDMA?
A. I just learn after June of 2018 that valsartan may be contaminated with the NDMA.
Q. When did you learn that, what day?
A. What day? I can't tell you what day. But that's the -- June or July time frame of 2018.
Q. Looking at your CV, there are six bullet points describing your responsibilities as general manager.
Do you see that?
A. Yes, I see that.
Q. The first one is, "Select and develop of new product for development pipeline."
Correct?
A. Yes.
Q. Does that include valsartan?
A. No. Usually we develop new

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product. Okay. Valsartan is a very old product. So that's not including valsartan.

Q. This says in the second bullet point, "Provide CMC service for NCE development."

What does that mean?

A. CMC service for the NCE -- NCE is new chemical entity, okay. We develop the, you know, chemical process and the manufacturing service to those, you know, new compounds, okay, new chemicals.

Q. The third bullet point says, "Providing process research and development scaleup and tech support services."

A. Yes. We develop the process research at the laboratory scales, and scale up is to kilogram scale at the lab and, you know, tech support for the pilot program manufacturing process.

Q. Let's break that down a little. Where you said providing process

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research and development, what is that specifically referring to?

A. Referring to when you have a process -- chemical process, you do the process starting, we call that process research. And once you find the process parameters, okay, you -- you know, you -- that's pretty much it. Let me stop right there. That's called process research.

If there's no process for a particular chemical, we develop a, you know, chemical process for that.

Q. What does scale up mean?

A. Scale up is in the laboratory scale, you're doing, let's say, milligram to gram scale chemical process. And at the laboratory, we trying this -- make sure this works, doing some feasibility studies to scale this up to, let's say, 100-gram scale or even kilogram scales.

Q. That's all in the laboratory?

A. Yeah, laboratory. Scale up

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is in the kilogram laboratory, what we call kilo labs.

Q. What is pilot scale? You mentioned that earlier?

A. Pilot scale is even bigger than the kilogram scale. Kilogram scale you can do, let's say, chemistry trying to, let's say, collect 100-gram or even up to kilogram scale of the part.

But in the pilot plan, you are using much bigger vessels. Okay. For vessel scale, you can use, let's say, 500 liters to 1,000 liters to making, let's say, tens of gram of the product, you can do like the pilot scale.

Q. Why do you go from the lab scale up to milligrams, grams, and kilograms within the lab and then go up to pilot scale? What is the purpose of moving up to larger quantities?

A. Because you can make a chemical conversion or process that work for in the laboratory, you know, on a small scale size, let's I said, from gram

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to even kilogram. You work that well.

But if you want to further scale that up, we do in the pilot -- pilot plan, pilot scale. In that case we making, let's say, tens of kilograms of materials. The process work in the laboratory may not work well in the pilot scale as you further scale it up because of the material transfer, or heat transfer, they are completely different product scales.

So that's why you have to do it that way, okay. Once after the pilot scale, the further scale is -- happens to be a commercial scale.

Q. So after pilot scale you go to commercial scale?

A. Yes, yes. That's usually the process, you know, is. From lab scale to the kilogram to the pilot scale, further scale up to the commercial scales.

Commercial scale depends on what -- how many quantity the batch size

you want to make and design the equivalent setup that fits the purpose.

Q. This scale-up process from lab to pilot and then to commercial, is this something that is required by good manufacturing practices?

A. Yes. Exactly. Because that is also common industrial, you know, practice up to today. It gives you much more confidence you can, you know, make the process happen. That's how you make the process happen in the commercial scale.

Q. When you said so that you can make the process happen, do you mean so the process will yield the product that you were expecting it to yield and meet the quality standards?

A. Yes, yes. That's basically -- is because the laboratory scale give you the -- let's say qualitative material. You have to prove that you can do to that in commercial scale. That's -- you have to go through

the process as we discussed.

Q. Is commercial scale when you're actually manufacturing for sale or is that a step before you're manufacturing to sell to customers?

A. Commercial scale is for sale.

Q. Okay. Does the risk assessment process continue at both the lab scale and pilot scale?

A. Yes, the risk assessment is the same way, doing the same way.

Q. And tell me if I understand this. As you go from lab and then up through pilot scale and add more quantity of material, you continue the risk assessment because you may get different data as you add more product and you start to do the process on a larger scale. Does that make sense?

A. Yeah. At the end you have to repeat the process. The laboratory scale and, you know, kilogram scale are only give you supporting data.

But sometimes we do laboratory scale, go straight to the pilot scale. Or sometimes you go straight to commercial scale to collecting data. But at the end, commercial scale data is the, you know, final data.

Q. When you say the commercial scale data is the final data, are you referring to as part of the risk assessment process?

A. Yes.

Q. So if I understand correctly, the risk assessment process starts in the beginning, and it goes all the way through actual manufacture for sale to customers. Did I understand that correctly?

A. You're not correct. Could you repeat that again?

Q. Sure. Do I -- am I correct that the risk assessment process starts at the lab-scale level, continues at the pilot-scale level, and continues at the

commercial scale as well?

A. Yes. That's supposed to be the process, yeah.

Q. Your CV says in the fourth bullet point, provide analytical method development and separation service. What is analytical method development? What does that mean?

A. That's the -- that's a good question, because in the -- in our capacity, we doing the new product research. So for the process research, you have to have a method to detect the, you know, the intermediates, the -- you know, so you have to develop a method to specifically detect those intermediates.

So we have to develop analytical method for each new product or for each new step of the product. And we also -- that's one part. Okay. Is that clear?

Q. Yes.

A. Okay. The next part is separation services. We do some of the

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separation for those, let's say, intermediates or impurities, okay, to get the reference standard, okay. We call that separation services.

Q. And when you said to get the reference standard, you mean the standards that are applied when the analytical testing is performed so that there's a reference standard to compare the results to?

A. Yes, because some of the material, let's say, for the new product development, those, let's say, intermediates or, let's say, impurities, they are not commercially available. So you have to, you know, separate it from the reactive standard, in order to get the reference data material to compare with so you know what you are testing.

Q. When you say, so you know what you are testing, is that referring to so that you know what the results you're obtaining through your testing match up to?

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MR. BALL: Objection to that.

THE WITNESS: Let me give you an example. How's that? Okay? Let's say you making -- you want to hear that?

BY MR. SLATER:

Q. Yes, that would be great.

A. Sorry?

Q. That would be great, yes.

A. So when you're making a compound A to B, let's say, right, the B is not a commercially available material. That's why you have to, you know, pure -- B to purify to get a structure identified to get the purity data so that you can use that as a reference, okay, for the future testing.

Q. Okay. The fifth bullet point, "Provide process safety and HAZOP and engineering solution consulting," does that have to do with safety in the manufacturing process?

A. Yes. That's called process

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safety, okay. It's -- you know, we doing the process safety assessment for all those chemical transformations, you know, material safety, process safety, you know, to make sure, okay, the process, you know, being transferred to the pilot scale, commercial scale is safe to run.

Q. The sixth bullet point says that you, "Develop green enzymatic technology for pharmaceutical production."

What is that referring to?

A. Oh, that's another section, okay. We develop the, you know, biological method let's say, for example, using enzyme to much better chemical transformations when we have the formations, you know, those new technology, in order to be more green, which means much less waste, you know, gas waste or liquid waste or, you know, solid waste.

That's a new area we have been working on.

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MR. SLATER: I think we can take that down. And then we're going to put up a PowerPoint presentation that I'm told is from July of 2013.

THE WITNESS: July 2013. Okay.

MR. SLATER: And I think Bates number is ZHP-01397317.

(Document marked for identification as Exhibit ZHP-225.)

MR. SLATER: And I think we should use the color version, Cheryll.

BY MR. SLATER:

Q. The document that we have on the screen, which I guess is Exhibit 225 --

A. Okay.

Q. -- is a PowerPoint we were provided and we're told that the date is in July of 2013.

Does this look familiar to

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you?
A. Yeah. It's a SynCores PPT.
Q. You said it's the SynCores -- did you say PPP?
A. No, PPT. PowerPoint presentation.
Q. Got it. What use was made of this -- rephrase.
How was this PowerPoint used? Who would have used it?
A. This is -- you know, I don't know -- actually, this version, I haven't seen it, okay. But this is used when you introduce your company to the clients, you know, for that purpose.
Q. The pages are not all numbered. So I'm having trouble giving Cheryll a page number to go to.
MR. SLATER: I'm trying to get to a page more than halfway through that says "R&D Capabilities."
THE WITNESS: Okay.
MR. SLATER: But, Cheryll,

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you'll have to -- you're going to have to scroll ahead. I'll look and see if the pages in the other -- the black and white version, but I don't have -- I don't have it. So you're just going to have to scroll forward. Good. Thank you.
BY MR. SLATER:
Q. This page describes some of the research and development capabilities for SynCores. And I'm interested in the middle one, analytical, where it says, "Genotoxic impurity analysis."
Do you see that?
A. Yeah, I see that.
Q. And what is your understanding of what that means, genotoxic impurity analysis?
A. That -- you said the document was produced when?
Q. The document was dated in 2013.
A. Okay. The genotoxic

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impurity, that was the concept, you know, we slowly trying to grasp on it. The ICH M7 was not formally being set until 2016, okay. But we slowly know there are genotoxic impurities, the concept at that time.
Q. Okay. What does genotoxic impurity analysis mean?
MR. BALL: Objection. Vague.
THE WITNESS: I'm sorry.
MR. BALL: I said objection. Vague.
THE WITNESS: Okay. Do I have to answer that?
MR. BALL: Yes, you need to answer it to the degree you can.
THE WITNESS: Okay. It could have caused the gene to mutate, okay. That's called genotoxic impurities.
THE VIDEOGRAPHER: I'm sorry to interrupt. I'm the videographer.

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Doctor, can you center yourself on the screen, please. Thank you.
THE WITNESS: Let me -- okay. Is that better?
THE VIDEOGRAPHER: Yeah, that's much better. Thank you very much.
BY MR. SLATER:
Q. Can I ask you -- rephrase.
What is your e-mail address at SynCores?
A. HGu@SynCores.net, I think, yeah, .net, yeah.
Q. We're looking at the indication of genotoxic impurity analysis. And you told me genotoxic impurity is an impurity that can cause a gene to mutate, correct?
A. Yes. I said potentially that could cause gene to mutate.
Q. Is it considered -- well, rephrase.
What does it mean, as used

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here, genotoxic impurity analysis? What is a genotoxic impurity analysis as used here?

A. That was, you know, the PPT was done before I was even join the SynCores, okay, but I can tell you this, after I join in 2014, okay, that was only a new concept. That was maybe only a, you know, fashion statement in 2013.

MR. SLATER: Cheryll, I don't want to take it down. But if you can put up the e-mail dated March 7, 2014, as Exhibit 226.

(Document marked for identification as Exhibit ZHP-226.)

MR. SLATER: We'll come back to the PowerPoint, but let's do that first.

THE WITNESS: Okay.

BY MR. SLATER:

Q. We've put on the screen Exhibit 226, which is a March 7, 2014 e-mail sent by Jie Wang, J-I-E, Wang, to

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you and copied to a few people.

Do you see that?

A. I see that.

Q. And the e-mail says, "Eric," and that would be you, right?

A. Yes.

Q. "Eric, please see attached previous SynCores presentation, which in my view serves the purpose and principle for basically covering both research and development and production capabilities, detailed illustration of development capabilities, and services of/by SynCores. Of course, you may want to update here and there as appropriate so we can finalize it today." Signed Jie Wang.

Do you see what I just read?

A. Yes. I saw it, yep.

Q. Okay. And I can represent to you that this -- the PowerPoint that we've been going through is the SynCores presentation 2013/7/12 PowerPoint referred to as an attachment to this

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e-mail.

Do you see that?

A. Okay. Yes.

Q. Does this help to refresh your memory at all that you saw this PowerPoint in 2014?

A. It doesn't, because there is so many version of the SynCores PPT.

Q. Okay. Let's go back to the PowerPoint.

A. Okay.

Q. The term "genotoxic impurity analysis."

A. Mm-hmm.

Q. What is -- what is a genotoxic impurity analysis? Please tell me what that means.

MR. BALL: Objection. Vague.

THE WITNESS: Do I have to answer that?

MR. BALL: Yes, unless I instruct you not to answer, Dr. Gu, you have to answer.

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THE WITNESS: Okay. Genotoxic impurity analysis, I don't know what -- because that's only few words put on a PPT. Maybe they tried to impress some clients or not, okay. Maybe they did some genotoxic impurity analysis back in 2013.

But if you ask me what is genotoxic impurity analysis, I can't tell you, because that's just a PPT.

BY MR. SLATER:

Q. Does SynCores perform genotoxic impurity analysis?

A. At what time frame? Could you put it in the context?

Q. Now. Currently.

A. Yes, we do. Because we have, you know, a process to do the genotoxic impurity, you know, assessment protocols. We not necessarily do analysis, but first thing we do is use -- there's two database post by the FDA to

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do computer analysis first.
If you call that analysis, too, okay, but the software wasn't available back in 2013. Nowadays, we do have two software to do the -- to do the analysis today.
Q. You said that genotoxic impurities analysis was a new concept in 2013? Did you say that?
A. That's the concept being discussed in industry, okay.
Q. Are you aware that the FDA had a guidance for injury dated -- rephrase.
Are you aware that the FDA had a guidance for the industry titled "Genotoxic and Carcinogenic Impurities in Drug Substances and Products: Recommended Approaches," dated in December 2008? Are you aware of that?
A. That was -- you know, that was a discussion version, a draft. I think I saw that, yeah. That was way -- long way back.

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Q. When ZHP developed the zinc chloride process, it knew that it had to undertake a genotoxic impurity analysis, correct?
A. Could you -- could you repeat the question again? When ZHP what?
Q. Actually, I'll rephrase it differently.
When SynCores and ZHP developed the zinc chloride process, they knew they had to conduct a genotoxic impurity analysis, correct?
MR. BALL: Objection. Compound.
THE WITNESS: I don't know how to -- let me think, okay, how to answer this question.
When SynCores develop the zinc chloride process, we have to do genotoxic impurity analysis?
Is that what you're asking?
BY MR. SLATER:
Q. Yes.

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A. Yeah, based on our knowledge at that time, you know, if there was a suspected genotoxic impurity in the process, we will do the analysis.
Q. When ZHP -- well, rephrase.
Was SynCores involved in the development of the manufacturing process for valsartan with sodium nitrite quenching?
A. In the lab scale, yes.
Q. With regard to the valsartan sodium nitrite quenching process, was SynCores and ZHP responsible to perform a genotoxic impurity analysis?
MR. BALL: Objection. Compound.
THE WITNESS: When you know, you will do the analysis. If you don't know okay, you will not.
BY MR. SLATER:
Q. I'm sorry. I didn't understand the answer. If maybe -- can just say that again?
A. Let me say it. Okay. When

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you know, you know, there is a suspected genotoxic impurity in the process, you will do the analysis. If you do not know at that time, okay, if you don't know, what are you going to do?
Q. That's why identification of the potential impurity is so important as part of the risk assessment, correct?
MR. BALL: Objection. Mischaracterizes his earlier testimony.
THE WITNESS: That's a general -- general question.
Could you repeat with specificity? What are you talking about?
BY MR. SLATER:
Q. It's important to identify potential -- rephrase.
It is important to identify potential genotoxic impurities so that the risk assessment can look to see if they're being formed as part of the risk assessment, correct?

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MR. BALL: Same objection.
THE WITNESS: Like I say, again, okay, if you know, you will look for it.
Okay. If you do not know, what are you looking for?
BY MR. SLATER:
Q. And as I asked you before, that's why it's so important to identify the potential genotoxic impurities so that you can look for them, correct?
MR. BALL: Objection. Asked and answered.
THE WITNESS: You asked me the question several times. Let me say it again.
If you do know, you will look for it. If you do not know, you are not looking for it.
That's not --
BY MR. SLATER:
Q. If you don't know because you performed an inadequate evaluation of potential impurities, then you have

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violated good manufacturing practices, correct?
MR. BALL: Objection. Compound.
THE WITNESS: That --
MR. BALL: I'm sorry. Objection, foundation.
THE WITNESS: Adam, you're very funny. Okay. You're trying to put the answer into my mouth several times already. Okay.
BY MR. SLATER:
Q. Could you answer my question, please?
A. Answer what? I forgot your question again. Okay. You asked me three times. You confused me. Okay. Could you repeat that again?
Q. If a manufacturer -- well, I'll ask it more specifically to your company.
If SynCores, who was working with ZHP, failed to identify potential genotoxic impurities because of a lack of

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adequate scientific analysis, that would be a violation of good manufacturing practices, correct?
MR. BALL: Objection. Foundation.
THE WITNESS: Okay. Like I said again, okay, at that time okay, it's knowledge based. If you knew, okay -- I think SynCores did a comprehensive study for that process already, okay.
In that time, okay, we didn't know, okay. Nobody knows. Even the FDA doesn't know. And the industry doesn't know. So I don't know -- your question or how to answer your question. But I'll just disagree.
MR. SLATER: Cheryll, do you have handy Exhibit 209 that we used last week? If you do, I'd like to pull it up.
Thank you.
(Previously marked

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ZHP-209.)
BY MR. SLATER:
Q. What's on the screen is Exhibit 209, which is titled "IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans." And it's dated May 1978.
Do you see that in front of you?
A. Yeah. It's a red color. It's difficult to read. Go ahead.
MR. SLATER: Let's go, if we could, Cheryll, to Page 36.
Perfect. Thank you.
BY MR. SLATER:
Q. Looking now at the third paragraph on Page 36. It says, in the first sentence, "It has been known since 1865 that the reaction of dimethylamine hydrochloride with sodium nitrite at an acidic pH yields NDMA."
Do you see that?
A. Yeah, I'm reading that, yeah.

Q. You would agree with me that SynCores and ZHP were responsible to know of that potential chemical reaction when they were developing the valsartan manufacturing processes, correct?

MR. BALL: Objection. Vague.

THE WITNESS: We did many research and also the reference search, okay -- has been suggested -- because this is a very, very, you know -- dimethylamine hydrochloride with sodium nitrite at an acidic pH, it's all very vague and, you know, general comments. They didn't specify what the exact condition was.

So I don't know how to answer your question. It has been suggest. It doesn't have any data to it.

Okay. I just consider this as a general statement.

Yep. Go ahead.

BY MR. SLATER:

Q. I'll ask again.

A. Mm-hmm.

Q. When ZHP was developing the zinc chloride process, ZHP was responsible to know that dimethylamine and sodium nitrite, which could be converted to nitrous acid in the manufacturing process, could react and form NDMA, right?

A. Yeah, what are you referring to? Because we don't use dimethylamine. We use DMF.

Q. So you agree that ZHP and SynCores were responsible to know what I just asked you when they were developing the process; is that correct?

A. No, that's not correct.

Q. Well, did SynCores and ZHP know in 2011 that dimethylamine and nitrous acid could react to form NDMA? Did they know that?

MR. BALL: Objection.

Compound.

THE WITNESS: Like I said, okay, we used DMF. We are not using dimethylamine. And it also says dimethylamine hydrochloride, okay. Read it carefully.

And at an acidic pH. I don't know what you are referring to by acidic pH. PH 6.5 is acidic. But pH is minus two? I don't know. I just could not comprehend this. Okay. I just don't -- this is general comments.

MR. SLATER: Cheryll, you can take this document down.

Let's go, if we could, to -- if you can go to 208.

Exhibit 208, Cheryll, the guidance for industry from the FDA from 2008. Let's put that up if we could.

(Previously marked ZHP-208.)

BY MR. SLATER:

Q. On the screen we have Exhibit 208, which is the FDA's guidance for industry, "Genotoxic and Carcinogenic Impurities in Drug Substances and Products: Recommended Approaches," again dated in December 2008.

A. Mm-hmm.

Q. You are familiar with this document, correct?

A. Yes, I'm familiar with that.

MR. SLATER: Let's go, if we could, to Page 7, please, Cheryll.

BY MR. SLATER:

Q. In Section 4-A the title is "Prevention of Genotoxic and Carcinogenic Impurity Formation."

Do you see that?

A. Yeah. Could you -- could you expand that a little bit. It's very small.

Q. This -- rephrase.

The section says -- rephrase.

This states, "Since

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drug-related impurities presumably provide limited, if any, therapeutic benefits and because of their potential to cause cancer in humans, every feasible technical effort should be made to prevent the formation of genotoxic or carcinogenic compounds during drug substance synthesis or drug product manufacturing."

Do you see what I just read?

A. Yeah, I saw it.

Q. And what I just read, as a matter of risk assessment, SynCores was responsible to know that information in 2011, correct?

A. Yeah. 2011.

Q. ZHP was also responsible to know this information as well, correct, in 2011?

MR. BALL: Objection. Vague.

THE WITNESS: 2011, yes. That -- yeah. Okay. Go ahead.

BY MR. SLATER:

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Q. In developing the zinc chloride manufacturing process, every feasible technical effort needed to be made to prevent the formation of genotoxic or carcinogenic compounds during drug substance synthesis or drug product manufacturing, correct?

A. That's not correct. Further read that okay. "However, we recognize that completely preventing the formation of or removing an impurity of concern may not be possible in many cases."

Do you read that?

Q. I'm sorry. Is that your answer?

A. Keep reading. Okay. Finish the last sentence of Section A for me, please.

Q. Is that your answer to the question, sir?

A. No, it's not. Because that's only part of my answer. Okay.

This is the only draft version of the guidance at that time. We

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are still discussing that because there are many things that we do not understand. We humans are not capable of everything. This is the one case. This is scientific questions.

Q. Do you know that your company -- well, rephrase.

Do you know that ZHP cited this guidance in submitting the updated DMF in December of 2013 to the FDA?

MR. BALL: Objection. Beyond the scope.

THE WITNESS: This --

MR. BALL: Eric, let me finish, please.

Objection. Outside the scope of his 30(b)(6) topics.

Go ahead.

THE WITNESS: Adam, could you repeat the question again?

BY MR. SLATER:

Q. Yeah. With regard to this FDA guidance, are you aware that ZHP cited to it in submitting the DMF for the

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zinc chloride process to the FDA in December 2013?

MR. BALL: Same objection.

THE WITNESS: I didn't know, because submitting DMF is not a part of my job.

BY MR. SLATER:

Q. Did SynCores confirm that there were no -- rephrase.

Did SynCores confirm the genotoxic impurity profile for the zinc chloride process as part of its work in 2011?

MR. BALL: Objection. Foundation.

THE WITNESS: I don't know how to answer.

Adam, could you make this question more direct.

BY MR. SLATER:

Q. Did SynCores do a genotoxic impurity analysis in connection with the zinc chloride process?

A. Did SynCores do a genotoxic

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impurity analysis with the process; is that right?
Q. With the zinc chloride process, correct.
A. Like I said, okay, we -- I'm sure -- you know, I wasn't with the company at that time. But I'm sure we did that. If we knew, okay, there was a genotoxic impurity, we would do analysis.
Q. Well, did SynCores look for nitrosamine impurities in the zinc chloride process manufacturing process?
MR. BALL: Objection. Vague.
BY MR. SLATER:
Q. I'll ask it differently. When SynCores was helping to develop the zinc chloride process, did it identify NDMA as a potential impurity that had to be tested for?
A. As I said, okay, at 2011, we did the process development based on the ICH guidelines. And at that time, okay, we follow the GMP protocols. And we

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didn't know the NDMA was the potential impurity in the process. And the industry didn't know. The FDA doesn't know. And nobody knows at that time.
Q. You didn't know that NDMA was a potential impurity of the process because the people responsible failed to do an adequate scientific analysis of the potential chemical reactions and degradants from those chemicals, correct?
MR. BALL: Objection. Mischaracterizes his earlier testimony.
THE WITNESS: No, I disagree. I answered that question many times already. I don't know how many times you want me to repeat that.
BY MR. SLATER:
Q. So is it your testimony that SynCores did a thorough scientific analysis of potential chemical reactions and missed NDMA as part of the thorough analysis?

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MR. BALL: Objection. Mischaracterizes his earlier testimony.
THE WITNESS: Do I have to answer that again? I answered this several times.
MR. BALL: You have to answer the question, okay. Feel free to answer yes or no. If you have to qualify it, feel free to qualify it.
THE WITNESS: Adam, I just disagree with you. It doesn't matter how you ask it.
We, SynCores, did a -- thorough studies at that time based on our knowledge about the valsartan process. We followed the cGMP guidelines. We follow the ICH guidelines. We did all we can.
But unfortunately, at that time nobody, including SynCores and ZHP, including all other

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company making valsartan, including FDA, EDQM, all of those regulatory agencies, nobody knows that.
BY MR. SLATER:
Q. Who at SynCores evaluated the potential for DMF to degrade or decompose and form other substances as part of the manufacturing process? Who was responsible for that analysis?
MR. BALL: Objection. Foundation.
THE WITNESS: Adam, your question is confused, okay. At that time? Doing what?
BY MR. SLATER:
Q. You said the question was confusing?
A. Yeah. Could you please ask more precise?
Q. Who at SynCores evaluated potential degradation of DMF as part of the zinc chloride process?
MR. BALL: Objection.

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Vague. Foundation.
THE WITNESS: At what time?
BY MR. SLATER:
Q. During the development of the zinc chloride process.
A. I don't know who because I can tell you this, okay. You know, of course, you know, we select a solvent based on stability. And I think that's good for the process.
MR. SLATER: Michelle, can you read that answer back for me, please, when you get a moment.
MR. BALL: Adam, we've gone an hour 20. Why don't we wrap up with one more question and take a break.
THE WITNESS: My breakfast should be -- should arrive.
MR. BALL: We're going to take a break here, Dr. Gu.
(Whereupon, the court reporter read back the requested portion of testimony.)

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BY MR. SLATER:
Q. Did anybody at SynCores evaluate the potential for DMF to degrade during the zinc chloride process when SynCores was helping to develop the zinc chloride process?
A. Okay. Adam, let me answer your question that way. Because DMF is a very stable solvent, it is commonly used in the industry widely, and it has a boiling point of 152 degrees celsius. And it's below our process temperatures.
And we believe the DMF was very stable at that time. And so are other companies that manufacture who are also using the DMF for the process. So we think, okay, that the DMF is very stable at that time.
Q. Is there any particular report that you're referring to when you tell me that the boiling point was analyzed in order to determine there was no risk of it degrading during the zinc chloride process?

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MR. BALL: Objection. Mischaracterizes --
BY MR. SLATER:
Q. Is that in a document somewhere?
MR. BALL: Objection. Mischaracterizes his earlier testimony.
THE WITNESS: Okay. Can we take a break now?
MR. BALL: No, go ahead and answer the question, Eric. Then we can take a break.
THE WITNESS: Because he's confuse -- Adam, I'm sorry, because your question is so confusing, okay, you know, I just --
BY MR. SLATER:
Q. I'm asking, is there a particular report or document that you're referring to that actually states the information you just said about evaluating DMF and its boiling point in

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connection with potential degradation of DMF. I want to know, is that documented anywhere back during the development process?
MR. BALL: Objection. Mischaracterizes his earlier testimony.
THE WITNESS: I don't know what you are -- you know, what report are you talking about for this particular process. You know, put it into context.
You know, what are you referring to?
BY MR. SLATER:
Q. Is there any document from SynCores or ZHP that documents that potential degradation of DMF as part of the zinc chloride process was evaluated and that somebody determined, because of the boiling point, it wasn't a concern?
A. If the boiling point was a concern, boiling point was the indication of how stable the solvent is.

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Q. Is there any document that has that information in it, that that was actually considered back when the zinc chloride process was being developed?
A. I don't know how to answer these questions. Okay. Let me state it again, okay.
The DMF was distilled, okay, off to make the DMF. It must be stable at that temperature, right?
MR. BALL: Okay, Adam. Can we take a break now?
MR. SLATER: Is he done with the answer? As long as he's done, we can.
THE WITNESS: Yeah, I'm done, okay. Because I tell you the DMF was distilled off to make the DMF solvent. It has to be stable at those temperatures; otherwise, DMF cannot be made.
MR. SLATER: All right. We can take a break.
MR. BALL: Thank you.

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THE VIDEOGRAPHER: The time right now is 8:25 a.m. And we're now off the record.
(Short break.)
THE VIDEOGRAPHER: The time right now is 8:42 a.m. We are back on the record.
BY MR. SLATER:
Q. Looking again at the PowerPoint that was provided to you in 2014, there was a page titled "Analytical Capabilities."
Do you see that?
A. Yes, I do.
Q. And this talks about process research and development and manufacturing support, correct?
A. Yes.
Q. The third bullet point under that says, "Identification of impurity, structure elucidation."
Do you see that?
A. Yes, I do.
Q. What does it mean,

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identification of impurity?
A. Identification of impurity is, you know, for the reactions, there might be side reactions. We trying to see -- excuse me, pardon -- to identify impurity could be found in the process or in the APIs or even in intermediates.
Q. That requires an analysis of the chemical reactions, correct?
A. Yes. We mainly focus on the main reactions.
Q. Well, you just said it. The main reactions and the side reactions have to all be evaluated, correct?
A. Yes. We focus on the main reactions.
Q. You keep saying you focus on the main reactions. You also have to evaluate the side reactions, correct?
A. Yes, when you say you should, a lot of things you should, yeah. But as I said, you know, we focus on the main reactions.
Q. Good manufacturing practices

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requires evaluation of the main reactions and the side reactions, correct?
MR. BALL: Objection. Vague.
THE WITNESS: The GMP says that?
BY MR. SLATER:
Q. Correct.
A. Yes, correct.
Q. The reaction whereby DMF decomposed to form dimethylamine, was that a side reaction?
A. That was not. That was not even side reactions. That's the, you know, solvent, you know, decomposing, okay.
Q. The reaction between dimethylamine and nitrous acid, was that a side reaction?
A. You know, we define a side reaction, is the -- you know, reactant, react with the -- you know, bi-part.
In this case, the DMF decomposed to DMA. That was not even a

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side reactions.
Q. The reaction between dimethylamine, which you referred to as DMA, and nitrous acid to form NDMA, is that a side reaction?
A. I don't know how to define that. Usually the reaction reacts with reactants in a different way. We call that side reactions.
Q. What do you call the reaction between DMA and nitrous acid that formed NDMA? What do you refer to that as?
A. We didn't know there's a DMA. We only know there's a DMF at that time. So nowadays you ask me the DMA with the sodium nitrite. I don't know how to call that. But that's the -- has nothing to do with the main reactants, okay. It's the, you know, acid and base used in reactions.
I don't know how to call that. I don't have a definition for that.

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Q. I'm sorry. I didn't meant to say -- that's a chemical reaction, correct?
A. Yeah. You can call that.
Q. What is structure elucidation? I see that word there. What does that mean?
A. Structure elucidation means, you know, when you did the reactions, you found an impurity in the process, you are trying to, you know, identify if possible.
If not, okay, you try to elucidate, okay, what's the potential structure could be.
Q. The fourth bullet point says, "Genotoxic risk assessment for API."
Do you see that?
A. Yes, I see that.
Q. What does that mean?
A. Genotoxic risk assessment, what does it mean by that? For the APIs. Okay.

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Q. What does that mean?
A. Let's say for the API, it's, you know, similar structure, that could be the risk -- could impose risk of genotoxic impurity. We assess that.
Q. The risk assessment for genotoxic impurity as part of the zinc chloride process was required by GMP, correct?
A. As I said, okay, the guideline for that time is a draft document. It's not commonly used for the industry yet, okay.
Q. So it's your testimony that a genotoxic risk assessment was not required by GMP when SynCores and ZHP developed the zinc chloride process?
A. I don't want you to confuse with GMP with genotoxic risk assessment.
The document that you just showed me, okay, that was only the draft version. It is not finalized yet.
Q. I'll ask again. Did good manufacturing practices require SynCores

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and ZHP to perform a genotoxic risk assessment as part of the development of the zinc chloride process?
MR. BALL: Objection. Asked and answered.
Go ahead.
THE WITNESS: Let me just rectify your concept. GMP is called cGMP, okay.
As the GMP guideline moving forward, it's called current good manufacturing practice.
As in this case, it's genotoxic impurity risk assessment still in the draft version here.
MR. SLATER: Michelle, could you read that answer back to me, please.
(Whereupon, the court reporter read back the requested portion of testimony.)
MR. SLATER: Cheryll, if you could, let's put up Exhibit 206 from last week's deposition,

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please. Please turn -- let's look at the cover actually.
(Previously marked ZHP-206.)
BY MR. SLATER:
Q. On the screen we have Exhibit 206, which is the EMA guidelines that were in effect from January 1, 2007 to January 31, 2018, titled "Guideline on the Limits of Genotoxic Impurities."
Do you see that?
A. Yeah, I see that line there in the middle.
Q. Would you agree with me that by 2011, the need to evaluate for genotoxic impurities was well established in the pharmaceutical manufacturing industry?
MR. BALL: Objection. Vague.
THE WITNESS: It is not -- could you let me read the document, you know? Don't just show me a line, okay. Can I read

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that?
MR. SLATER: Sure.
Let's go off the time so we're not -- the time stops running and you can read it. You have as much time as you want.
THE WITNESS: Can you scroll it down? How can I do that?
MS. CALDERON: Do you want to tell me where to go?
THE WITNESS: Keep going. Guidelines, yeah, okay.
MR. BALL: Dr. Gu, in the chat, you can pull the document up yourself. Do you remember how to do that?
THE WITNESS: I seem to see -- let's see.
MR. BALL: Cheryll, you may have to help him out with the exhibit number.
MS. CALDERON: Sorry. I was on mute. It's 206.
MR. BALL: So it might be a

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little more efficient, Dr. Gu, if you can just go into the chat and pull it up yourself.
THE WITNESS: Yeah, I just go the link, right?
MR. BALL: Yeah, yeah, go to the link, and then it's Exhibit 206.
THE WITNESS: Okay. 206.
MR. BALL: If you can just let us know when you're done looking at it.
THE WITNESS: Okay.
MR. BALL: Thank you.
THE WITNESS: Okay, I'm done.
MR. BALL: Okay.
BY MR. SLATER:
Q. You got me on a bite of my sandwich.
MR. BALL: I got up and had a bite too while he was reading it.
MR. SLATER: Okay. We can

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go back on.
THE WITNESS: Okay.
BY MR. SLATER:
Q. This document was known to SynCores and ZHP by 2011, correct?
MR. BALL: Objection. Compound.
THE WITNESS: I don't know -- I don know whether --
BY MR. SLATER:
Q. I've got to ask it differently because counsel is objecting as a compound question. So let me figure out if I understand it, so I'll ask the question differently.
By 2011, SynCores was aware of this document, correct?
A. Yeah, I assume, yes, because this is the common document.
Q. By 2011, ZHP was aware of this document, correct?
A. You know, I just can suppose that. I suppose they know. But I don't know exactly if they know or not.

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Q. Just to be clear about something -- well, let me rephrase.
SynCores is a wholly owned subsidiary of ZHP, correct?
A. Yes, correct.
Q. And I think you said at the early part of the deposition, you consider yourself to be an employee of ZHP, correct?
A. Like I said, yes or no, I was employed by the SynCores. SynCores is owned by ZHP. So in a sense, yes.
Q. For example, the computer you're using during this deposition came from ZHP, correct?
A. Yes, that's correct.
MR. SLATER: Let's turn to Page 4 of 8, please, Cheryll.
BY MR. SLATER:
Q. Section 4, titled "Toxicological Background," states, "According to current regulatory practice, it is assumed that in vivo genotoxic compounds have the potential to

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damage DNA at any level of exposure and that such damage may lead/contribute to tumor development.
"Thus, for genotoxic carcinogens, it is prudent to assume that there is no discernable threshold and that any level of exposure carries a risk."
Do you see what I just read?
A. Yes, I see.
Q. When SynCores was involved in the development of the zinc chloride process, SynCores was aware of that information that I just read, correct?
A. Yes. I assume, yes.
Q. When ZHP was developing the zinc chloride process, ZHP was familiar with that information, correct?
A. I wouldn't say for ZHP or for other people. But I'll assume that's the case.
Q. The same answers would apply to the TEA process with sodium nitrite quenching, correct?

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MR. BALL: Objection. Vague. Time frame.
THE WITNESS: Yeah.
MR. SLATER: Let's go to Page 6 of 8, please, Cheryll. Perfect.
BY MR. SLATER:
Q. In the first full -- excuse me.
In the first -- sorry.
In the first full paragraph, this states some structural groups were identified to be of such high potency that intakes even below the threshold of toxicological concern, or TTC, would be associated with a high probability of a significant carcinogenic risk," citing, Cheeseman, et al., 1999; and Kroes, et al, 2004.
"This group of high potency genotoxic carcinogens comprises aflatoxin-like, n-nitroso and azoxy compounds that have to be excluded from the TTC approach. Risk assessment of

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members of such groups requires compound-specific toxicity data."
Do you see what I just read?
A. I see what just read, yes.
Q. And you see that the term "risk assessment" is used in connection with the evaluation of those potential carcinogens, correct?
A. Yes.
Q. And the n-nitroso compounds would include NDEA and NDMA, correct?
A. I don't know. It's called n-nitroso compounds, yeah, because n-nitroso compounds, it includes many of those. I assume NDMA and NDEA is part of it, yes.
Q. And certainly by 2011, the risk assessment performed by SynCores needed to evaluate whether or to what extent such genotoxic impurities might exist in the manufactured product, correct?
A. Adam, would you repeat your question again?

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Q. Sure. When SynCores was involved in the development of the zinc chloride process, it knew it had to evaluate as part of its risk assessment to make sure that no such genotoxic impurities would be in the product, correct?

MR. BALL: Objection. Vague.

THE WITNESS: Adam, let me answer your question that way.

SynCores work assessed risk, you know, of the genotoxic impurity based on the knowledge they have known for the process.

BY MR. SLATER:

Q. Did SynCores evaluate the potential decomposition of DMF into DMA as part of the zinc chloride process?

A. At that time, okay, SynCores, we believe the DMF is very stable solvent. We didn't know it decomposed to the DMA and the particular reaction conditions.

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And also, if you want to know when it's decomposed to DMA or not, you need to specify a method to do that. I believe we didn't know, and we didn't do that.

Q. So am I correct that was not considered as part of the risk assessment?

MR. BALL: Objection. Asked and answered.

THE WITNESS: You just changed my answers, okay.

We do whatever possible with the knowledge base at that time, we did our risk assessment for the process.

BY MR. SLATER:

Q. As part of SynCores development of the sodium nitrite quenching process for the TEA process, did SynCores take into account the possibility that triethylamine hydrochloride could contain diethylamine or dimethylamine?

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A. SynCores -- I don't believe SynCores did the triethylamine process. We did at SynCores the DMF process.

Q. Did SynCores or anybody at SynCores do any sort of a scientific literature search regarding the chemicals and the chemical reactions that were going to occur in the zinc chloride process it was developing?

A. I'm sure we did the, you know, literature search based on what's available to us.

MR. SLATER: Cheryll, what I'd like to do is first put up, I guess, the -- it looks like we have the English and Chinese language versions. It looks like they have the same Bates number for the contract review form. I have ZHP-00000215.

Can we put that up, please.

MS. CALDERON: Sure. Just give me one minute.

MR. SLATER: Yeah, the --

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exactly. That's the Bates number. ZHP-00000215. It's a Chinese-language document.

Okay. This is exhibit -- what number are we up to? Is it 227?

MS. CALDERON: Yes.

(Document marked for identification as Exhibit ZHP-227.)

BY MR. SLATER:

Q. Looking now at Exhibit 227, can you tell me what this document is, please?

A. It's called the, you know -- ZHP's, you know, contract assessment table.

Q. That's the title?

A. Yeah.

Q. In the section on the details of the contract, which is the second section, does this talk about Shanghai SynCores Technologies, Inc., and what its role would be?

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A. You want me to translate that to you line by line?
Q. No. If you could answer my question, please.
A. The second -- the second line, or second -- you know, row, it just says they're going to, you know, hire Shanghai SynCores to do the, you know, process development and with some of the, you know, targets. Let's say, one, two, three, four. And that's about it. And how much the contract will pay.
Q. I see Items 1, 2, 3, and 4 in the section of the details of the contract.
Do you see that?
A. I see that, yes.
Q. With regard to impurities, what does that say in Number 3?
A. Number 3 says single -- single -- a single -- one single impurity should be equal or less than 0.1 percent.
Q. What does Number 4 say about impurities?

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A. Number 4 is the total impurity equal or less than 0.3 percent.
Q. Does the document state anything regarding genotoxic impurities?
A. It didn't put into words, but I'm sure it's all in the, you know, let's say, the total impurity or single individual impurity.
Q. My question is, does this document specifically address genotoxic impurities?
A. On the paper, reading word by word, no.
Q. If you could, could you explain to me in general terms, what was the arrangement between SynCores and ZHP regarding the zinc chloride process? What was SynCores hired to do?
MR. BALL: Objection. Vague to time frame.
THE WITNESS: Do I have to answer?
MR. BALL: Yes, you need to answer. Sorry. Unless I tell you

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not to answer, you have to answer.
THE WITNESS: Okay. The ZHP hired Shanghai SynCores to develop a new process with the target of one, two, three, four.
Is that clear?
BY MR. SLATER:
Q. Let's go through one and two. Number 1 says "Content, HPLC" -- well, actually let me ask you this. What does Number 1 say?
A. Number 1 is we call the content or called the assay by HPLC, 98.0 to 102.0 percent.
Q. And what does that represent, 98 to 102 percent?
A. That's usually is the API content. We call that weight by weight assay. Okay. So using HPLC to analyze that, the content should be between 98.0 to 102.0, you know, range.
Q. And in the details of the contract section, Number 2, what does that state?

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A. It says the reaction yield should be greater or equal to 40 percent.
Q. And what is the reaction yield? What is that referring to?
A. We try and make A plus B equals C. We want to, let's say, to see the recovery is -- we call that yield. Okay. It should be more than -- or equal or more than 40 percent.
MR. SLATER: Cheryll, could you go, if you could, to the page with Bates Number 217 on it, please.
BY MR. SLATER:
Q. Towards the top of the page I see a section that has a one, two, three listed.
Do you see that section?
A. Yes, I see that.
Q. What's the heading for that section? What does it say is the heading?
A. The heading is -- Number 1 is the, you know, the content for the

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development work.
Q. What is the heading though? What is the title of that section?
A. You are talking about the SynCores responsible for ZHP to develop a valsartan new process.
Q. Is that what it says right above the Number 1?
A. Right above Number 1 is the contract technical content and the requirement.
Q. Number 2, next to the Number 2, does that say requirements?
A. Yeah. It says requirements.
Q. And under the heading of requirements, Number 1, does that refer to, "Upon completion of process development"?
A. Mm-hmm.
Q. "Party B" -- and party B would be SynCores, correct?
A. Yeah. Party B, yes.
Q. "SynCores shall complete three validation batches."

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A. Mm-hmm.
Q. And what else does it say about those three validation batches?
A. You mean keep -- what are you -- what are you asking?
Q. If you could read the rest of the sentence, please.
A. Okay. "Shall complete three validation batches. Yield and the quality meets the requirement, or India you know, require, you know, a range.
Q. Does it refer to a successful test of the process?
A. Test of the process of what?
Q. In Number 1 that you just read from, does it refer to a successful test of the process?
A. Yeah. Yes. Successful test of the process in the pilot scale.
Q. Is that saying that SynCores would conduct the pilot scale study?
A. No. On the paper it reads that way. Usually the pilot scale is on the commercial side.

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Q. So the reasonable understanding of this agreement would be that after the development of the process at the lab-scale level by SynCores, that ZHP would then perform the pilot scale testing?
A. Yes, that's correct.
Q. Tell me if I understand this right. Only ZHP could conduct the pilot scale testing because only ZHP would have the facilities that would be able to conduct that level of testing, as compared to SynCores?
A. Yes. SynCores does not have the equipment or the facility to do that.
MR. SLATER: Cheryll, can you scroll down to the bottom half of the page, please. Cheryll? Bueller? Thank you.
Had to get a "Bueller" into this deposition.
BY MR. SLATER:
Q. Looking now at the bottom half of this page, which is Bates Number

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217 are the last three digits. I think this indicates in its heading, "Technical Indicators and Parameters to be Met."
Is that a fair reading of that?
A. Yes. That's item Number 1, yeah.
Q. And Number 1, what does that say, Number 1. If you could just read the first Number 1.
MR. BALL: Adam, do you want him to translate it? Or do you want him to give the gist of it.
MR. SLATER: I think it's probably best if he just reads it to me.
THE WITNESS: In Chinese? Or translate into English, right?
BY MR. SLATER:
Q. Thank you.
A. Okay. That's the content, HPLC should be between a range of 98.0 to 102.0 percent.

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Q. I'm sorry. I'm talking about the Number one above that.
A. Oh, Number one above that.
Q. Yes.
A. Okay. Supposed to reach the technical indication in the parameters.
Q. Let me take a stab at it. Tell me if my reading is a fair reading.
A. Okay.
Q. And I'm now -- rephrase.
I'm looking now at the bottom part of the page, that's Page 1, which is Bates 217, the second section for the technical indicators and parameters to be met. There's a Number 1 underneath that.
A. Mm-hmm.
Q. Which I read as, "The purity and content of the final product sample provided by Party B," which we've agreed is SynCores, "shall meet the quality standards of the valsartan process, and the quality standards are provided as follows."

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Do I have that read right?
A. Yeah. You know, yes, you are right. But if you're reading this directly, it didn't say that much. Okay. You just said a lot, which is not reflected in the -- in this document.
Q. Was my reading of it a fair understanding of what it was stating?
A. Yeah. I mean, actually, yeah, you can say that.
Q. And then the four items below are the four items that we went through previously, correct?
A. Yes, the same.
Q. And those quality standards were set in advance by ZHP, correct?
A. That's correct. That is the ZHP's requirement.
Q. If SynCores determined based on its own risk assessment that there was a potential genotoxic impurity that could be created due to the chemical reactions in the process, would SynCores have been required to advise ZHP of that?

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MR. BALL: Objection. Speculation.
THE WITNESS: Yeah. If we knew okay, then we would discuss that with ZHP, or report to ZHP.
BY MR. SLATER:
Q. I think this document actually states the amount paid to be per the contract. Can you tell me what that amount was?
A. If you scroll back up, I think -- I think it's 200,000 -- if I remember correctly. 200,000 -- keep going back, yeah, up, up, up.
Where did I read it? If you keep going up. Oh, it's not there. Then it's going down somewhere. I saw it -- I think I saw it somewhere. It's 200,000 RMB somewhere, going down, and also said how the amount is going to be paid. Going down. Right there.
The contract total amount will be 200,000 RMB and will be paid in -- first, we were paid 100,000 RMB.

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The second payment would be another 100,000 RMB.
Q. And did SynCores perform this contract and get paid on this contract?
A. Oh, I didn't talk to the -- assume, yeah, they perform the contract, they get paid.
MR. SLATER: Cheryll, can you go to the page where the Bates number is 222, please. Can you scroll up a little bit more? Perfect.
BY MR. SLATER:
Q. Tell me if I'm correct, that in the box on the left, the second box from the top, all the way to the left, it has -- it lists the developer, Party B, as SynCores?
A. Yes.
Q. And it lists a legal representative for SynCores. Who is listed?
A. Mr. Chen.

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Q. Mr. Chen, the chairman of ZHP?
A. Yes.
Q. Do you know why he's listed as the legal representative for SynCores?
A. I don't know why, because when they set up the company, Mr. Chen was the legal representative. I think that's -- has been changed since then.
Q. Do you know what Mr. Chen's involvement was, if any, in this contract or the work done under this contract?
A. None.
Q. When you say none, what do you mean?
A. He didn't involved at all, okay, for the SynCores business.
Q. Have you spoken with Mr. Chen, the chairman of ZHP, about the NDMA and NDEA impurities in valsartan?
A. At what time?
Q. At any time, have you discussed that with him?
A. I think so, yes. That was

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like sometime in the late 2018 when we discovered there was a problem, we had a few meetings together.
Q. Was it just you and him or were there other people involved too?
A. I remember there was other people involved as well.
Q. What, if anything, do you recall him stating about the impurities?
A. Yeah. He ask us, every department, do whatever we can to find out what -- you know, what is it, okay. And then we arrange for the risk assessment work to be done.
Q. You're saying he arranged for the risk assessment work to be done, or he told you and the other departments to do so?
A. Told us to do so, yeah.
Q. Were the results reported to him?
A. Usually he is not involved into that much, with the technical part. He just being told of the results.

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Q. Do you know if the results were reported to him?
A. I think so. He must know the results.
Q. Do you know what, if anything, he did in response to learning the results of the risk assessments?
A. Adam, could you -- could you repeat the question again? I didn't quite --
Q. Sure. Do you know what -- sure.
Do you know what Mr. Chen, the chairman of ZHP, did in response to learning the results of the risk assessment regarding the impurities that were discovered in 2018?
A. Usually we give the suggestion. So what we are supposed to do, how we are going to report and do what, you know, do what supposed -- you know, what has to be done, he approves that. He usually allocate resource, you know, funding for us.

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Q. Do you know what, if any, specific concerns he had about this?
A. Yeah, to make sure that we follow all the guidelines, we follow -- do whatever we can to -- you know, to protect the patients and, you know, receive -- for example, recall the materials, all those other things.
Q. Do you recall him stating that, or is this what you're assuming he did?
A. I think I heard -- you know, in a meeting, he said about that, okay.
Q. When was that meeting?
A. I don't remember exactly, but that was -- that was when we learned about it in a meeting to discuss this matter.
Q. When you say you learned about it, what do you mean by that? Learned about what?
A. Learned about there are potential genotoxic impurity in the valsartan, while we are still confirming,

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developing a method. And Mr. Chen said let's do that first, okay, while we're still doing the research, to take some proactive steps to protect the patients, okay.

Q. Who else attended that meeting?

A. I think the regulatory people, the quality people, the manufacturing people participated -- participated here.

Q. Where did this meeting take place?

A. I remember it's in the ZHP.

Q. Where in ZHP?

A. ZHP, the head of quality, Shengzhou, it's in the Zhejiang province.

Q. And which room did it take place? Do you recall?

A. There's quite a few meeting room. I'm sure it's one of them on the first floor.

Q. Do you know if minutes were taken of that meeting?

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A. I don't know. Because I'm not -- I don't know.

MR. SLATER: Let's pull up, Cheryll, if we could -- we can take that down. Exhibit 199.

(Previously marked ZHP-199.)

BY MR. SLATER:

Q. Do you see the document that we've put on the screen as Exhibit 199?

A. Yes. It says Peng Dong ZHP 199, yes.

Q. Are you familiar with this document?

A. I think I saw it in the past.

Q. This is the SynCores research and development report of valsartan (SC-1141), correct?

A. Yes, correct.

Q. Looking at Number 1, the project target, it talks about optimization of the process. And I want to stop there.

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What does optimization mean?

A. Optimization means, okay, when you have a process to make, you know, a particular compound, you want to do the process optimization to fine tune the process parameters.

We call that -- in order to maximize the yield and give you better quality, intermediate or product, or better safety profiles, good quality of product, that's called optimization.

Q. This says that one of the goals was to improve the total yield of the valsartan, correct?

A. Yeah. That was one of the goals, yes.

Q. How would that be beneficial to improve the yield?

A. Improve the yield, you can reduce the waste. That always will be beneficial to the environment.

Q. What are the other benefits of improving the yield?

A. Other benefits improving

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yield could lower the cost.

Q. One of the benefits of improving the yield is to lower the cost, correct?

A. That's not always the case because you improve the yield, you know, that's with the -- the assumption is that you have to produce better quality materials. If that assumption couldn't be met, it's useless to improve the yield.

Q. In the case of the valsartan zinc chloride process, improving the yield lowered the cost, correct?

A. No. Like I said, again -- okay, let me repeat it one more time.

Improve the yield, lower the cost under the precondition is better quality material to be made.

If that precondition could not be met, you know, forget about improving the yield.

Q. So you're saying with valsartan's zinc chloride process, it was

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not better quality than the prior process?
MR. BALL: Objection. Mischaracterizes his earlier testimony.
THE WITNESS: You know, if the product is not better quality, the FDA would not approve that. This drug business is heavy regulated. You have to meet the FDA requirement first before we can do anything else.
BY MR. SLATER:
Q. In the case of valsartan, the zinc chloride process, was the yield improved and the cost lowered?
MR. BALL: Objection. Compound and outside the scope.
THE WITNESS: You know, we are developing a process with many goals, okay. If the yield was improved, I assume the cost would be lower, but that's not always the case.

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BY MR. SLATER:
Q. Well, in this case, that's what occurred, right?
MR. BALL: Objection. Outside the scope.
THE WITNESS: I didn't know, because let's say you change the process, you're using different chemicals, sometimes even the yield is improved, but the cost might not be lower.
BY MR. SLATER:
Q. Well, okay. So you don't know the answer to the question? Is that what it is?
A. I didn't know the -- because the cost -- the cost, you know, how much cost was reduced, that number would be generated at the commercial side. We don't do the -- we just do a rough estimation. But the final number come out of the commercial side.
Q. I'm just trying to make sure I understand. With regard to the

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question of whether the yield of valsartan was improved and the cost was lowered as a result, you don't know the answer, correct?
MR. BALL: Objection. Compound. And outside the scope.
THE WITNESS: Adam, like I said, again, for research people, you know, we doing the -- the goal is to make better quality materials to improve the yield. That's always the objective.
But at the end, what's the final cost for the material going to be at the commercial scale is decided by the commercial manufacturers, because calculating the cost is quite a complicated process.
BY MR. SLATER:
Q. You said that SynCores' goal was better quality materials, correct?
A. Yes. As I said, it has to be, because if you making changes, you

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know, if you don't make a better -- equal or better quality material, the FDA won't approve that.
Q. And it's your understanding that the FDA approved the material manufactured by the zinc chloride process?
A. Yes. FDA, we send the change to FDA, to the EDQM, to those regulatory bodies, okay. They approve that.
Q. Did the FDA actually test the material and approve it?
MR. BALL: Objection. Outside the scope.
MR. SLATER: I'm responding to his statement, so I think I can --
MR. BALL: Adam, Adam, I'm allowed to make my objection.
MR. SLATER: Yeah, I know. I'm just saying I think because he said it, I have to follow up on his answer.

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MR. BALL: You don't have to follow up. You can follow up if you choose to.
MR. SLATER: I feel compelled to do so.
THE WITNESS: Okay. So I can answer that, right?
MR. BALL: Go ahead.
THE WITNESS: Okay. Adam, you're asking the FDA take the material to do testing? Right?
BY MR. SLATER:
Q. Right.
A. You might have to talk to the regulatory people. But as far as I understood, okay, the FDA come to, you know, audit or inspect how you do the analysis. But the FDA, sometimes they do take samples back to analyze that.
But in this case, I don't know. I would assume -- I wouldn't -- you know, I do not know. I just don't know whether the FDA take the samples back and do an analysis or not.

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Q. You said SynCores' goal was to develop better quality materials.
As you sit here now, you would agree with me that the material was not better quality. It actually contained NDMA, which was an unintended genotoxic impurity, correct?
MR. BALL: Objection. Mischaracterizes his earlier testimony.
THE WITNESS: Adam, okay, as I said, okay, for the pharmaceutical business, you have to make an equal or better quality materials in order to be approved by any regulatory bodies, okay?
You know, did I answer your question? Or do I have to repeat myself?
BY MR. SLATER:
Q. As you sit here right now, the valsartan manufactured by the zinc chloride process which was developed by SynCores produced valsartan with an

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unacceptable quality risk, correct?
MR. BALL: Objection. Mischaracterizes his earlier testimony.
MR. SLATER: I'm not characterizing testimony. I'm making an informed --
MR. BALL: Well, what are you -- are you asking a question?
MR. SLATER: I'm asking if he agrees with that statement.
THE WITNESS: Adam, let me just -- Adam, the process was meet the FDA requirement. It has been approved by the FDA and the EDQM.
BY MR. SLATER:
Q. Did SynCores intend to develop a process that would yield valsartan that contained NDMA?
A. Adam, no.
Q. Speaking for SynCores, do you agree that the contamination of the valsartan with NDMA was unacceptable?
MR. BALL: Objection.

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Vague.
THE WITNESS: Adam, okay, you know, would you -- is this a question or is this a statement?
BY MR. SLATER:
Q. It's a question. Do you agree with my statement that the NDMA impurity was unacceptable?
A. Could you put this into content? This is a general statement, okay.
If you ask me now, okay, after we go through all those we know, then I can answer your question. But at that time, we didn't know.
So, Adam, could you repeat your question again? I don't know how to answer your question now.
Q. As you sit here right now, you agree with me that the NDMA contamination of the valsartan manufactured by the zinc chloride process was unacceptable? Do you agree with that statement?

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MR. BALL: Objection. Vague. Asked and answered.
THE WITNESS: Adam, are you talking about now?
BY MR. SLATER:
Q. Yes.
A. 2021, or after 2018, June, yes, that is not acceptable.
Q. Looking at this agreement --
MR. SLATER: If we can scroll down to the bottom half of the first page, please, Cheryll.
Perfect. Thank you.
BY MR. SLATER:
Q. This sets forth a specification of crude valsartan.
Do you see that?
A. Specification of crude, yes.
Q. Just so that we have our vocabulary straight between us, what does that mean, crude valsartan?
A. Crude valsartan is the crude product in the reaction. It hasn't been final purified yet by reconciliation

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process. That's called crude.
Q. What, if any, impurities are identified in these specifications?
A. I'm sorry. What was your question again?
Q. Under Number 1, the specification of crude valsartan, what, if any, impurities are addressed?
A. You know, D-isomers is specified in there. And the impurity H, okay, is -- and other unknown impurities. And the total amount of impurity allowed is in the table.
Q. Who established those specifications?
A. The specification of the crude valsartan is established by the ZHP.
Q. Did SynCores utilize gas chromatography-mass spectometry to evaluate potential impurities in the valsartan it was developing per this contract?
A. Adam, could you -- could you

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rephrase that again?
Q. Sure. Did SynCores use gas chromatography-mass spectometry to try to identify unknown impurities that may have developed in the development of the zinc chloride process?
A. The answer is SynCores use the GC. GC-mass was not available for SynCores at that time. So the GC-MS is not so commonly seen in the -- in the, you know -- the commercial side or other manufacturers.
We use GC, okay, to analyze the -- residual solvents, GC alone.
Q. Number 2 at the bottom of the page says, "Specification of final API."
MR. SLATER: Cheryll, if you could then scroll to the next page so we can see the table that would be great. Thank you.
BY MR. SLATER:
Q. And just to be clear, when this says specification of final API,

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what does that mean as shown on this table?
A. I didn't see it say -- I didn't see it say anywhere this is final API. Maybe that's being blacked out.
Q. No. That was at the bottom of the prior page.
MR. SLATER: Cheryll, please show him again just so we don't have a question.
THE WITNESS: Oh, yeah, yeah, I see it. Specification of final API. Okay. Scroll down. Thank you. Yeah.
Adam, what's your question?
BY MR. SLATER:
Q. Starting with, what is the final API, just so we have our vocabulary straight?
A. Final API is the API -- is a finalized API, is finished API after the purification process. That would be used for the formulation manufacturer to make the final dosages. That's called final

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API.
Q. Who set the specifications set forth on this table?
A. Those specifications have to meet the FDA requirements. So is -- asking who's setting those specifications? ZHP, FDA, EDQM, all those regulatory bodies.
Q. So the zinc chloride process, based on your understanding needed to meet the preexisting specifications in order to be able to continue to be sold?
A. Yes, you have to -- like I said, okay, the zinc chloride process has to produce the final valsartan equal or better quality than the other process in order to be -- you know, in order you can get approval from the FDA or other regulatory bodies and then you can sell on the market. That's the preconditions.
Q. Bear with me a second. I'm trying to find a specific page.
A. I'll grab a water, okay, one

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second.
Q. Go ahead.
MR. SLATER: Cheryll, go to -- the Bates number is 76 -- well, I'll give you the last two digits, 60. And I think it's sideways. You're going to have to do your rotation thing. Maybe not. Good.
MR. BALL: I think it's only sideways in the Chinese version, or maybe it got rotated.
MR. SLATER: Yeah, I think she's -- yeah, because Cheryll is faster than both of us.
BY MR. SLATER:
Q. Okay. Looking at the center of this page.
A. Okay.
Q. It says, Number 2 -- and I guess -- rephrase.
Looking at the center of this page, it says, "The other catalyst systems were also used in this reaction.

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In the system from Huahai, zinc chloride/DMF/NaN3," which I think is sodium nitrite, "is the best conditions."
Do I have that correctly? Do I have that correct?
A. Yes. That's translated version. Yes, that's correct.
Q. What does that mean, when this characterizes the zinc chloride process as the best conditions? What is that referring to?
A. Usually we referring to that, after we did all those testing, for example, using different catalyst besides zinc chloride, and different solvent systems and a combination of solvent and sodium azide.
You know, we compare all those different studies, okay, and the process, you know, parameter formulations, okay, different temperatures, rinse, you know, for all those conditions.
After we had done that, then

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we analyzed the valsartan being produced at different conditions, you know, based on the quality material produced, the yield, the process safety, and, you know, the process capabilities. Have to assess all those parameter together.
But the main focus is the quality has to be equal or better than the, you know, the original process, that precondition. You know, this is the best condition that could do that, okay, to meet the requirements.
Q. You have to have the required quality, but it also had to increase the yield in order to be acceptable per the contract, correct?
A. Yes. You know, as I said, okay, you have to, first of all, make it equal or better quality material. And then you can talk about other things, like improving yield, improving process safety, reduce the cycle time, all those other parameters.
MR. SLATER: Cheryll, go if

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you could, to Page 75, is the last two digits.
BY MR. SLATER:
Q. This is the final page of this report. And Number 6 says, "Future improvement."
A. Mm-hmm.
Q. "The synthesis process of crude valsartan and the purification process, including the solvent system, need to be further optimized at the pilot scale."
And then in the bottom right it has Shanghai SynCores Technologies, Inc., January 20, 2011.
A. Mm-hmm. Yes.
Q. What is that referring to in terms of what needed to be further optimized at the pilot scale?
A. That's -- that is, you know -- almost you can find those in many, many of the reports, because we did the laboratory scale, okay. They're going to take that into the pilot scale.

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Sometimes it's very easy to scale up. Sometimes they might encounter some difficulties.
This is a cover statement that we put on it to protect SynCores, you know, to make sure SynCores gets paid. It is a very general statement, okay. We put that almost on all the reports.
Q. I think you told me earlier in the deposition a way that the development process is supposed to flow, you're supposed to have a lab scale, then a pilot scale, and then go to commercial scale, correct?
A. Yes. Correct.
Q. The date of January 20th, 2011, does that represent the date on which SynCores completed its work on this process and handed that over to ZHP?
A. We issue report for the ZHP, yes. That's probably, you know -- we finish our work and hand over to the ZHP.
Q. I'm being told that we're

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over an hour and that we're supposed to take a break; is that correct?
A. Yeah.
MR. BALL: It's up to you. We can go -- I was trying to go about an hour 20. But it's up to you if you want to take a break now. That's fine with me.
MR. SLATER: Let's take a break, because I just -- it's a good transition point.
MR. BALL: Okay. That's fine. Thanks.
THE VIDEOGRAPHER: The time right now is 9:58 a.m. We're now off the record.
(Short break.)
THE VIDEOGRAPHER: The time right now is 10:13 a.m. We're back on the record.
(Previously marked ZHP-217.)
BY MR. SLATER:
Q. On the screen is a document

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marked as 217, and I'd appreciate if you could tell me what this document is, if you know. And if you need to scroll through, we can scroll through the first couple pages for you.
A. Yes, please. Scroll a couple pages for me.
MR. SLATER: Go ahead Cheryll, show him this page slowly, and then the next page.
And you can tell her to stop if you need it stopped.
THE WITNESS: Okay. Go ahead. Keep going, slowly, yeah. Yeah. Go ahead. Go ahead, yeah. Keep going.
MS. CALDERON: It's an 88-page document.
THE WITNESS: I get a rough idea of it. That's fine. That's okay.
MR. BALL: Adam, I don't know if you heard him, he said okay. He's seen enough of it.

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THE WITNESS: Yeah, I got an idea, yeah.
BY MR. SLATER:
Q. All right. Can you tell me what this document is, please?
A. It's the application for the, you know, technical project, okay. And also it's a feasibility study report for valsartan. The topic name is, you know, hypotensive drug valsartan, production process and, you know, for process improvement. That's the project.
Q. Well, who was involved in doing this project?
A. Based on the document you show me, the responsible units or company is ZHP.
Q. And who were they contracting with in this agreement?
A. This one we're contract with ZHP.
Q. Was there a university involved in this project?
A. I didn't see that. But

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under -- in the document it should -- but on this page right here, it says the responsible company or unit is called ZHP.
Q. I think we're going to have to go through it a little more to get this. I'm told that this is a draft application seeking funding to support a valsartan research project to be carried out by Zhejiang University of Technology?
A. No, because the document show me the page right here, the responsible units or company is ZHP, Zhejiang Huahai, you know, ZHP. It doesn't say anybody else.
Q. Are you saying this is an agreement by ZHP with itself?
A. No. This is the application to seek the project, you know, for the process improvement from the government, okay.
Q. I think -- all right. We were -- I was saying what you were saying, but I was saying it inartfully.

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So let me try this again.
A. Mm-hmm.
Q. This was ZHP applying to get funding to have this project performed with Zhejiang University of Technology, correct?
A. No. If in this page, okay, if you -- one, two, three, four, five -- the fifth line, right there, okay. It says Zhejiang Huahai. That's ZHP. It didn't say Zhejiang University.
Q. All right. You know what? We'll come back to this when I can give you some more precise information, because I do want to go through this, but not now through this process.
A. Okay. Maybe -- okay.
Q. If you're telling me it's not with that university, then I'll accept that for now and then perhaps come back to it later.
A. No, from the page, the document show me so far, I only see Zhejiang Huahai, ZHP.

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Q. Right. Are you familiar with Zhejiang University of Technology having any involvement at all with doing any research in connection with the valsartan project?
A. I haven't seen a document that relates to the Zhejiang -- you said Technology University, not Zhejiang University, right?
Q. Yeah, Zhejiang University of Technology, I was told.
A. Okay. Zhejiang University, yeah, that's the -- I heard about they were involved in early days, but I don't see in the document.
Q. When you say you heard about them being involved in the early days, what are you referring to?
A. When I talk -- when I try to prepare for the deposition, also talking to people that I know are involved in the project early days. They tell me they work with the Zhejiang University of Technology in the past.

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MR. BALL: Adam, I'm assuming you're eventually going to round this back into the deposition topics.
MR. SLATER: This has to do with the evaluation of the process.
MR. BALL: That's unclear to me so far that that has anything to do with the evaluation process. That's why I asked you, are you eventually --
MR. SLATER: I don't know. I mean, I can't tell you more than that's what this contract is for. That's what I'm told about all the reviewers who reviewed the document, that that's the purpose of it.
BY MR. SLATER:
Q. Okay. Why don't we do this, why don't we go to page -- Bates Number 183.
A. 183. Hold on. Hold on. Go

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back a little bit. Okay. Keep going down one more page. Stop right here.
Yeah, I see Party B is the Zhejiang University of Technology on the right side.
Q. You said the university is Party B, correct?
A. Yeah. Actually this is -- Party A is ZHP. Party B is the Zhejiang University of Technology.
Q. And if we turn back now to the page with the 183 on it. See if that -- I'm going to show it to you and ask you if that helps.
A. Okay.
MR. SLATER: That's good.
BY MR. SLATER:
Q. If this helps you to be able to tell me what the purpose of this project was, as part of the overall valsartan project?
A. Okay.
Q. Did I miss the answer to the question?

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A. I'm sorry?
Q. You didn't answer the question yet?
MR. BALL: No, I don't think he understood there was a question pending.
MR. SLATER: Okay. Yeah, I just realized that we were all both sitting here.
BY MR. SLATER:
Q. Does that help up -- well, let me ask you this.
What was the purpose for which this project was -- well, rephrase.
What was the purpose of this project as part of the overall valsartan project?
A. You know, if you -- if you read the title in the first page, the project starts at the 2011 some time, finish in 2013. And this is the application for the funding from the government, for the further improvement process.

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Q. In terms of the development of the zinc chloride process, was any of this work relied on by SynCores or did SynCores do its work independently?
A. Because this document only in the SynCores file, SynCores didn't participate in this, you know, project. Because you show me, this is application form. I don't know if this is being approved, project being carried out, or what's -- you know, what was happening.
Q. To your knowledge, was this project carried out and relied on at all by ZHP?
A. I don't know because I didn't, you know, ask. And this is the first time I saw it. And this is an application for funding, okay, from the government, for the process improvement. But SynCores, okay, SynCores didn't do anything with this -- has any relationship with this so-called application.
MR. SLATER: All right. We

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can take that document down.
Now what I'd like to do, Cheryll, is if we can go to ZHP-00493875.
(Document marked for identification as Exhibit ZHP-228.)
BY MR. SLATER:
Q. This is a letter that was sent by ZHP to the EMEA -- rephrase.
This is a letter dated November 14, 2018. The date, I can tell you, comes from the metadata.
A. Mm-hmm.
Q. The date's not on the document. But that's the date in the metadata.
A. Mm-hmm.
Q. This -- new question.
This November 14, 2018 letter was written by ZHP and signed by Jenson Ye, vice president of quality of ZHP, to the EMA and EDQM regarding their joint inspection of ZHP's facilities

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September 10 to 13, 2018. Are you familiar with this?
A. Yes. I know that -- I know that inspection, yes.
Q. You did not personally attend that inspection, correct?
A. I think I was there. That's 2018. I believe September. I think I was there.
Q. This says in the letter, "Object: Submission of CAPA plan to joint inspection between EMA (AIFA/AEMPS) and EDQM on 10-13 September 2018."
A. Mm-hmm.
Q. These are European regulatory agencies?
A. Yes. I think they are Italian agencies and Spain, you know, EDQM, and those agencies, yes, joint inspections.
Q. The letter says, "We refer to the e-mail received on October 18, 2018, sharing the list of deficiencies the inspection team reports that it

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observed during the joint EMA EDQM inspection conducted on 10-13 September 2018. Please find attached the CAPA plan and relevant documentations as attachments."
Do you see that?
A. I see that, yeah. Could you expand that a little bit because the letter is very small.
Okay. Thank you. It's better.
Q. There's some bullet points down below.
MR. SLATER: If you can scroll up a little bit, Cheryll, to get the bottom. Perfect.
BY MR. SLATER:
Q. This says in that first bullet point, "The risk assessment has taken account of the mechanistic chemistry."
I want to stop there. What does mechanistic chemistry mean as it's used there?

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A. That's called mechanistic chemistry, is the mechanism, okay, you know, how a particular compound was, you know, reacted, which atom to atom to making bonds, okay. That means if you had a Compound A, we want to know how Compound A was formed in the process. That's called mechanistic chemistry.
Q. You know, I neglected to ask this before. I just want to make sure for the record.
MR. SLATER: What exhibit number is this?
THE WITNESS: You're asking me?
MR. SLATER: No.
MS. CALDERON: 228.
MR. SLATER: I'm sorry. What?
MS. CALDERON: 228.
MR. SLATER: 328?
MS. CALDERON: 228.
MR. SLATER: Okay. Yeah, it sounded like we skipped 100 there.

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MR. BALL: Yeah, I heard 328 also, Adam, and I was like whoa.
BY MR. SLATER:
Q. So going back to where we were, "The risk assessment has taken account of the mechanistic chemistry, the likely sources for introduction of contaminants at the key steps of the method of synthesis so as to address the potential hazards with a view to qualifying and quantifying the levels of risk so that appropriate measures are put in place to control and/or minimize the occurrence of process-related contaminants such as NDMA and NDEA."
Do you see the paragraph I just read?
A. Yes, I did. It's right here.
Q. When ZHP refers to qualifying and quantifying the levels of risk, what does that mean?
A. Qualifying and quantifying the level of the risks, what does that

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mean? Is that they want to, first of all, to, you know, qualify, see how much is in there, and quantify it to see if the level of -- is below the TTC.
Q. With regard to the TTC, do you recall we went through the EMEA guidance earlier, and it said that with certain compounds, including n-nitroso compounds, you don't use the TTC approach?
A. You know, yes, that was the document that you showed me earlier. But up to today we are, you know, even talk with the FDA, EDQM, we are back into the -- you know, using the TTC to calculate the allowable limits. That is happening now.
Q. Are you testifying that the TTC approach is being used with regard to NDMA and NDEA at this point?
A. No, no, no. Put it in context. Nitrosamine, Okay. NDMA and NDEA is a part of the nitrosamine as a category of the compounds.

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Q. But you're not testifying that the TTC approach is being applied to NDMA or NDEA as impurities in drugs, are you?
MR. BALL: Objection. Vague.
THE WITNESS: I don't understand -- I didn't quite comprehend your question. Could you rephrase that?
BY MR. SLATER:
Q. You testified that the qualifying and quantifying of the risk was directed to establishing the TTC.
I then asked you to confirm and I'm asking you now, you're not saying that the regulatory agencies have told you they are going to apply the TTC approach to nitrosamine impurities, correct?
A. I just -- you know, I'm a little confused. Okay.
Q. Okay. I'll ask it --
A. Please simplify your

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question a little bit.
Q. You mentioned the TTC approach.
A. Mm-hmm.
Q. Why did you mention that?
A. Because TTC approach is the common, you know, standard. We have to have a standard, right? That's the very common standard to use.
Q. And then I asked you before, you understand that per the documents that I showed you earlier, the TTC approach is not applied to nitrosamine impurities. You understand that?
MR. BALL: Objection.
THE WITNESS: No, I don't, because, Adam, as this -- as we gain more and more understanding of the genotoxic impurity, the standard is changing, okay. It's always, you know, to optimizing the process.
It's kind of confusing, because we're talking about --

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sitting over here talking about the NDMA and NDEA for the valsartan.

But as you recall, okay, when the case -- when this issue happened back in 2018, we talked to the U.S. FDA. They set the limits to 1 ppb level, okay.

After, let's say, the metformin, ranitidine happen in the case, it's back to the TTC level again now, It's back to .3 ppm.

So as you know, as I said before, for the cGMP practice for the FDA guidance, always changing, as we gain more and more understandings, okay.

So I don't know how to answer your question. But this is the case, okay.

BY MR. SLATER:

Q. I guess since you introduced the subject, I think it's worth talking

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about for a few moments.

A. Sure.

MR. SLATER: Let's go back, Cheryll, to Exhibit 206, please.

Let's go with the cover first of this page, to orient ourselves. I mean the cover of the document, the first page of the document.

MS. CALDERON: The first page of 206?

MR. SLATER: Yep. Thank you.

BY MR. SLATER:

Q. To orient ourselves, this is the guideline on the limits of genotoxic impurities from the European Medicines Agency dated June 28, 2006, correct?

A. Right.

Q. And according to this document it was valid January 1, 2007 to January 31, 2018, correct?

A. Yes.

MR. SLATER: Let's go now to

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Page 6 out of 8, please.

BY MR. SLATER:

Q. In the first full paragraph it says, "Some structural groups were identified to be of such high potency that intakes even below the TTC would be associated with a high probability of a significant carcinogenic risk," citing Cheeseman, et al., 1999, and Kroes, K-R-O-E-S, et al., 2004.

"This group of high-potency genotoxic carcinogens comprises aflatoxin-like n-nitroso and azoxy compounds that have to be excluded from the TTC approach. Risk assessment of members of such groups requires compound-specific toxicity data."

You see what I just read obviously, right?

A. Yeah. I just -- I read it.

Q. So according to the European Medicine Agencies, they made it clear they do not apply the TTC approach to nitrosamines, correct?

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MR. BALL: Objection. Mischaracterizes the document.

THE WITNESS: So if that's not the case, then what is it then? What's the limit?

BY MR. SLATER:

Q. Are you aware that limits have been set?

A. From this document, I don't see where the limit is being set. If this is not the limit, then what is the limit?

Q. Well, let me ask you -- actually, let's go back to your question back to me. You asked me what's the limit.

A. Mm-hmm.

Q. The first step is that the risk assessment is supposed to identify the existence of the impurity, correct?

A. Yeah, you have to know that, okay. First of all, you find out if this is existing in the process.

Q. And then --

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A. Second of all -- go ahead.
Q. Once you identify that the impurity exists, then you go to the next steps of the risk assessment to analyze what is the risk and eventually determine whether or not it's acceptable or not to have that impurity and at what level, correct?
A. Yes. First of all, you have to know what -- you know, if this process -- if the impurity exist in the process.
Second of all, you have to develop a method specifically to detect if this is there, okay.
Third of all, you have to quantify that, okay. See, hope you have a reference data material to quantify that.
Fourth of all, then you set the limits, okay, see if it's below the set limit.
Q. Because ZHP never identified the nitrosamine impurities, it never was

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able to get to the second, third, or any other steps of the risk assessment process, correct?
MR. BALL: Objection. Vague.
THE WITNESS: Adam, at this time, okay, the entire industry, the FDA, the EDQM, nobody knows that was the risk that existed in the valsartan.
So putting this into content, okay, no one knows at that time back before existed in valsartan back in 2011.
BY MR. SLATER:
Q. Okay. I'm asking now about ZHP. The company that manufactured and sold the drug, okay? I'm only asking about ZHP.
A. Okay. You are asking ZHP, but I don't think ZHP was the only one making valsartan and sold in the U.S. market.
Q. Well, the subject of this

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deposition is ZHP, what they did and what they know. So that's what I'm asking you about. So that's what I'm attempting to address in these questions.
A. Okay.
Q. You would agree with me it's not an acceptable response for ZHP to have failed to do an adequate risk assessment, but then point the finger at another company and say, "Well, they failed to do an adequate risk assessment also, so we're not so bad."
That's not an acceptable response, right?
MR. BALL: Objection. Foundation. Mischaracterizes his testimony.
THE WITNESS: Adam, I didn't say that, Adam.
I just don't know how to answer your question. You keep going backwards and forwards with these questions, okay.
Just -- let me just tell

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you, okay. ZHP at that time didn't know, okay, there was a risk with the, you know, the GTI in the valsartan.
We did whatever we can. We follow the ICH guidelines, we follow the cGMP guidelines to do the research, to do -- to manufacture the products, which approved by the EDQM and FDA.
And I think we did our best, you know, to make sure the valsartan meets the EDQM and also FDA's requirements.
BY MR. SLATER:
Q. When ZHP developed the zinc chloride process, was any other manufacturer in the world manufacturing valsartan by the zinc chloride process, to your knowledge?
A. You know, I wouldn't speculate. But I'm sure there were.
Q. I'm asking if you know.
A. It's on the record?

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MR. BALL: Yeah, go ahead and answer, I mean --
THE WITNESS: I'm sure -- I'm sure there are other people in the same process doing that.
BY MR. SLATER:
Q. Well, let's break that down then. Who was using the zinc chloride process identical to ZHP's process before ZHP? Which manufacturer?
A. You know, Adam, you're talking about identical. That's 100 percent identical?
Q. Right. The same exact process, the same chemicals, the same solvents, the same specifications, everything. Was there another company before ZHP that was utilizing that process?
A. Adam, we talk to the people in the same field. I wouldn't speculate on identical, per se, okay. But I'm sure there are other people using similar process, using zinc chloride, also the

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DMF solvent systems.
Q. Who? Who was? Please tell me.
A. Adam, you're talking about the identical process. I wouldn't say who. I don't know who. If it is identical, I don't know. Because there are more than ten producers, you know, globally.
Q. When ZHP developed the zinc chloride process, it was attempting to differentiate itself from other manufacturers for the purpose of accumulating market share, correct?
MR. BALL: Objection. Outside the scope.
THE WITNESS: Adam, that's not part of my responsibility. I'll tell you one more time. When we trying to improve the process, the number one goal, precondition, is making better quality product. Okay. In the meantime, if we can, to improve the yield, reduce

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waste.
BY MR. SLATER:
Q. Let's come back to your statement from a couple of moments ago.
A. Okay.
Q. During the time -- well, rephrase.
When ZHP began to manufacture and sell valsartan with the zinc chloride process, which other company or companies in the world were using the same process to manufacture valsartan?
MR. BALL: Objection. Speculative.
If you can answer, please do.
THE WITNESS: Okay. You know, Adam, as I said before, there are more ten producers of valsartan in the field. We talk in the conference with other people. I know there were some people doing that.

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BY MR. SLATER:
Q. Who?
A. Adam, I wouldn't give the names, because I'm not 100 percent sure. Okay. I'm not sure it's 100 percent identical. But I wouldn't give names.
Q. If two companies -- or if two -- rephrase.
If two or three other companies were using the same process as ZHP independently, the zinc chloride process, and all of the companies, ZHP and the others, failed to identify the potential for nitrosamine impurities, are you saying that makes all of them have an excuse, or does that mean all of them failed to do an adequate risk assessment?
MR. BALL: Objection. Mischaracterizes his testimony. And compound.
THE WITNESS: Adam, you say that. I didn't say that, okay.
BY MR. SLATER:
Q. Then I guess we'll come back

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to where I originally was. I'm asking about ZHP and what ZHP did.
A. ZHP did whatever possible to improve the process, to make sure that we make better or equal quality product, to follow all the ICH guidelines, to follow the cGMP guidelines, to gain approval from the FDA and EDQM for the valsartan product. That's for this case. That's what has been done.
Q. Are you saying that it was impossible for ZHP to identify the potential for nitrosamine impurities with the zinc chloride process? Are you saying that was impossible to figure out?
MR. BALL: Objection. Mischaracterizes his testimony and vague.
THE WITNESS: Put a time frame, the content.
BY MR. SLATER:
Q. When ZHP developed the zinc chloride process, are you saying that it was impossible for ZHP to identify the

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potential nitrosamine impurities as part of the process?
MR. BALL: Objection --
THE WITNESS: That was back --
MR. BALL: Eric, let me finish, please.
Objection. Mischaracterizes his earlier testimony.
Go ahead and answer.
THE WITNESS: Okay. That's back in 2011. And, you know, it's because of detecting a low level of the genotoxic impurity, it requires many things, okay.
First of all, you have to -- you have the knowledge to know, okay, it could exist in the valsartan product.
The second thing is you have to develop a very specified method with the high resolution -- as you just mentioned GC-MS in order to detect that.

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So coming back to your questions, back in 2011, without those preconditions, yes, it's impossible to detect NDMA and NDEA in the valsartan product.
MR. SLATER: Cheryll let's take this document down and go to Exhibit 197, please.
Thank you.
(Previously marked ZHP-197.)
BY MR. SLATER:
Q. This was an article that was published in 2009. It's an article about DMF. Do you see that on the screen?
A. It says, "DMF, much more than a solvent." Is that what you're talking about?
Q. Correct.
A. It's Tetrahedron Letters, yeah. Okay.
Q. Tetrahedron, you know that journal, correct?
A. Oh, yes. It's popular

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journal.
Q. Well regarded, well respected, right?
A. It's not first tier, but it's second tier.
MR. SLATER: Let's go, Cheryll, to page -- it's the third page, right-hand column, Number 3.
THE WITNESS: It's very small. Adam, would you expand that a little bit? I can't read it.
MR. SLATER: You can make it bigger.
THE WITNESS: Okay. That's bigger than before. Okay.
MR. SLATER: You can -- you can slide it over, Cheryll. It's hidden, I think, behind the -- perfect.
THE WITNESS: Okay. Good.
BY MR. SLATER:
Q. Here in this article Number 3 says, "Source of carbon

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monoxide. DMF decomposes slightly at its boiling point to afford dimethylamine and carbon monoxide, this reaction occurring even at room temperature in the presence of acidic or basic materials. This observation has led to the use of DMF as a carbonylating agent."

Do you see that?

A. I see that.

Q. You would agree with me that it was publicly known in the chemistry field that DMF could decompose to yield dimethylamine, correct?

MR. BALL: Objection. Calls for expert testimony.

THE WITNESS: It's a scientific question, okay. That's a very general comment, okay. It's almost meaningless.

BY MR. SLATER:

Q. Well, this publicly available medical journal --

A. It's chemistry journal, Adam.

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Q. Thank you. This publicly available chemistry journal --

A. Mm-hmm.

Q. -- specifically points out knowledge that DMF can decompose to yield dimethylamine, correct?

A. You know what, because we are published in different journals, okay, the editor, okay, has to carefully review all those statements. This is a common, general statement. It didn't mean anything because reading the document says, okay, DMF decomposed slightly. What do you mean by slightly, first of all? At its boiling point to have formed dimethylamine and carbon monoxide. Okay. Show me data, number one.

Number two, the reaction occurring even at room temperature in the presence of some acidic or basic materials, you know, what kind of acidic or what kind of basic materials? You have to put this into content. We

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talking about scientific questions.

This is meaningless to us because I see those comments all the time. If the auditor didn't inspect or read those comments carefully, it's there. Those we call scientific garbage.

Q. That statement that I just read to you is a true statement, correct?

A. You know what, Adam, because we publishing papers, we publishing and thus, later find out that's not true. That's correct. Okay.

I wouldn't comment on those, because you can find many of the comments almost in many literature. This statement does not give you any details. That's -- that I consider as a general comments.

I want to say, you know, H2O, the water decompose even by the room temperature, slightly, by the way.

Q. Did anybody --

MR. BALL: Hold on. Hold on. I think he's getting some

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water.

THE WITNESS: I get some water. Sorry. Go ahead.

BY MR. SLATER:

Q. Did anybody from ZHP take into account the potential for DMF to decompose and yield dimethylamine and ask the types of questions you just asked in terms of at what temperature, under what conditions, and try to figure out whether or not there was a risk of DMF decomposing to yield dimethylamine in the zinc chloride process?

MR. BALL: Objection. Vague.

THE WITNESS: Adam, we discussed this, you know, previously, okay, just a while ago. DMF is commonly known and widely used solvent with boiling point above 152. It's a stable solvent. It's used widely.

And we, because all operating temperature is much

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below the boiling point, we consider DMF is stable.

So is the FDA and EDQM and other colleagues industrywise.

BY MR. SLATER:

Q. The use of DMF in the zinc chloride process was especially of concern because when dimethylamine was yielded due to decomposition, that then reacted with nitrous acid to form NDMA, correct?

MR. BALL: Objection. Calls for an opinion. Vague.

THE WITNESS: You know, Adam, when you're talking about DMF decomposing into DMA, even now, we found it decompose at ppm levels, all right.

So you consider that stable or not stable?

BY MR. SLATER:

Q. Is my statement correct?

A. Not correct.

Q. Well, isn't the root cause

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for the NDMA contamination of valsartan with the zinc chloride process tied to the degradation or decomposition of DMF to yield dimethylamine? Isn't that -- isn't that a critical part of the formation of NDMA in valsartan?

A. Adam, first of all, let's separate that. Okay. First of all, you're asking me DMF is a stable solvent or not. Okay. Let me answer that question. That is, okay.

Second part of question, later we found out, 2018, even, you know, minor decomposition of DMA produced -- DMF resulted in DMA, to the PPM level. It resulted in the NDMA, that answer -- that question, the answer is yes.

Q. So what is described in this medical journal article -- rephrase.

What is described in this chemistry journal is what occurred during the manufacture of valsartan with the zinc chloride process, correct?

MR. BALL: Objection.

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Mischaracterizes his earlier testimony.

MR. SLATER: I'm not characterizing his testimony. I'm asking him a question.

MR. BALL: Well, ask him a question. Don't say "correct," Adam?

THE WITNESS: Yeah.

BY MR. SLATER:

Q. Please answer.

A. Adam --

MR. BALL: You can answer, Dr. Gu.

THE WITNESS: It's not the same.

BY MR. SLATER:

Q. Did DMF degrade to yield dimethylamine as part of the zinc chloride process?

A. Yes. As I said, Adam, put this in content. At what level it decomposes?

Q. And when nitrous acid was

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applied and reacted with the dimethylamine, that resulted in the creation of NDMA, correct?

A. Yeah, that was after 2018 we did some sort of studies using high resolution GC-MS to find if that's the case at the ppm levels.

Q. Well, actually what happened was Novartis discovered it and told you that --

A. No, Adam --

Q. Let me finish. What actually occurred was Novartis discovered this and then advised ZHP. ZHP did not discover this on its own, right?

A. No. Adam, my side of version is this, okay. Novartis suspected unknown peaks. Then they contract this outside to a professional testing lab. Then they told us they suspect that's going to be the NDMA.

Okay. That's the story I know. Then we come back, okay, looking forward -- or looking carefully for the

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NDMA. Developed a specific method to detect that. Then we found out that's the NDMA.

Adam, that's my version of the -- that's my knowledge of what is this case.

Q. If Novartis had not brought this to ZHP's attention, there's no reason to believe ZHP would have figured this out by themselves, right?

A. Novartis only --

MR. BALL: Objection. Eric, please let me --

THE WITNESS: Go ahead.

MR. BALL: Eric, please let me get my objections out.

Objection. Calls for speculation.

Go ahead.

THE WITNESS: Okay. Adam, Novartis noticed there is unknown peaks is suspected to be NDMA, because, as you know, when you want to detect -- let's say an

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unknown peak or specified in compounds, you have to, first of all, you have to develop a specified method to detect that.

As far as I know, okay, we did many studies and develop the, you know, high resolution test method and provide it to the FDA, which becomes the final, you know, standard method to detect NDMA.

BY MR. SLATER:

Q. Let's go back to where we started with this scientific journal.

A. Okay.

Q. It was known in the chemistry community that DMF could decompose to yield dimethylamine under certain circumstances. That's a correct statement, correct?

A. Under certain circumstances, yes.

Q. There came a point when ZHP -- well, rephrase.

There came a point -- well

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let me ask you this. Rephrase.

Was it Shanghai SynCores that came up with the idea to use DMF in this process?

A. You know, Adam, it's not, because we screen many solvent, also combination of solvent, okay, to see which process will make better quality materials, improve the yield, to reach all those requirements.

Then we -- based on the data analysis, we found out, okay, using the DMF solvent system, give you the better quality materials, higher yield, all those, then we decide to use the DMF.

Q. Shanghai SynCores made the decision to use DMF in the zinc chloride process that came from SynCores, correct?

A. Adam, let me rephrase that again. Shanghai SynCores screen many solvent systems, and it turns out that DMF solvent system gives the better quality materials, and that's why finally DMF was chosen.

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Q. When you say better quality, you're not taking into account the fact that it was leading to the creation of NDMA, correct?

A. Adam, let's put a time frame. No one knows at that time.

Q. When -- well, rephrase.

The reality was that the zinc chloride process valsartan did not have acceptable quality because it contained NDMA in it, correct?

A. Adam, let me again put this time frame on this, okay. Now, after 2018, after we did so many research, discovered that's the case, it is not acceptable after 2018.

Q. Well, it wasn't acceptable in 2011, 2012, 2013, 2014, 2015, 2016, and 2017 either. You just hadn't discovered that it had the NDMA in the valsartan, correct?

A. Adam, we didn't know.

Q. You didn't know, and it wasn't acceptable. Just because you

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didn't know didn't make it acceptable, right?
MR. BALL: Objection --
THE WITNESS: You should ask FDA to answer that question, because no one knows. FDA doesn't know. EDQM doesn't know. Okay. Nobody knows.
You shouldn't ask the question to me, because I'm not regulatory bodies. I'm not in a position to approve that, okay.
BY MR. SLATER:
Q. So is the explanation from SynCores that even though you made this glaring error and didn't realize this risk, you're saying that other people missed it too, so it's okay that you did?
MR. BALL: Objection. Mischaracterizes his testimony.
THE WITNESS: Adam, nice try. State it again.
BY MR. SLATER:
Q. Are you saying that

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SynCores' failure to identify the risk of NDMA is excused because there are others who didn't realize this also?
MR. BALL: Objection. Mischaracterizes his testimony.
THE WITNESS: Adam, where did you get -- where did you get that idea from? I didn't say that.
BY MR. SLATER:
Q. Okay. So SynCores and ZHP are responsible for the fact that NDMA was in the valsartan, correct?
MR. BALL: Objection. Compound and mischaracterizes his testimony.
BY MR. SLATER:
Q. I'll ask the question again. ZHP is responsible for the fact that the NDMA was in its valsartan, correct?
A. ZHP and SynCores are what?
Q. Responsible for the NDMA being in the valsartan pills. You're not blaming someone else, right?

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MR. BALL: Objection. Mischaracterizes his testimony.
THE WITNESS: Whoops, sorry, I have to put on the power. It's running out of power. Hold on. Okay. There you go. Sorry, Adam.
Okay. Here you go.
BY MR. SLATER:
Q. Can you answer my question. You're not blaming somebody else for that, right?
MR. BALL: Objection. Mischaracterizes his testimony.
THE WITNESS: What to blame? Because no one knows at that time.
BY MR. SLATER:
Q. Let's go back through this now. SynCores decided to use DMF, correct?
A. SynCores does not decide anything. SynCores, based on scientific research, find the base solvent to make the better -- best quality materials.
Q. Did that scientific research

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include research into the potential decomposition products of DMF under the conditions of the zinc chloride process?
A. Adam, we have been coming back to discuss almost four or five times already. Do you really want me to repeat that?
Q. You just made a statement that the use of DMF was based on scientific research. So my question is whether that scientific research included analysis of the potential decomposition products of using DMF under the conditions of this process?
A. As we -- we humans, okay, we learn every day, as scientific issues being discovered more and more. Remember back in the old days, we think the earth is square.
Q. The question remains, did the scientific research relied on to use DMF include scientific research into the potential decomposition products of DMF used in the zinc chloride process?

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MR. BALL: Objection. Dr. Gu, if you can answer this yes or no, please do. To the degree that you need to provide an explanation, please do that.

THE WITNESS: Okay. Adam, I think I'm answering your question another way, okay. Nowadays, we are looking back -- we looking backwards, as we have the better equipment, more knowledge, yes, that's not acceptable now.

BY MR. SLATER:

Q. So let's look at what -- what it took to determine that it was DMF -- rephrase.

Let's look at what it took to determine this in -- rephrase, actually.

A moment ago you said that this is like when people thought the earth was square.

Are you saying that DMF decomposing to yield dimethylamine, as of

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2011, was the equivalent of people who thought the earth was square or was flat?

A. No. That's just -- you know, okay, DMF is a very stable solvent, okay. Even today, now, okay, it is commonly -- it's still is widely used in industry, okay.

DMF decomposing to DMA or carbon monoxide, at what levels? Now we are talking about GTI materials or ppm levels. We just discovered, learned that after 2018.

Q. SynCores knew when it decided to use DMF that it was -- rephrase.

If SynCores had reviewed, for example, this article, SynCores would have been required to ask the types of questions you're asking now, Meaning under what circumstances could that possibly happen when we manufacture valsartan, correct?

MR. BALL: Objection. Calls for speculation. And vague.

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Required by whom or what?

MR. SLATER: I'll ask the question differently.

BY MR. SLATER:

Q. Because SynCores and -- rephrase.

Because SynCores never took into account potential decomposition of DMF to yield DMA, it never evaluated the risk that DMA would react with nitrous acid to form NDMA, correct? That's a correct statement, correct?

A. I'm trying to comprehend. What do you mean by "correct"?

Q. Is that right? Is that accurate?

A. Because when SynCores did the process improvement, we assess the risk, okay, forming the impurity. That's why you see the specification says any unknown impurity should be below 0.1 percent. That's the FDA -- ICH guidelines, okay.

We are searching for any

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impurity. You know, we have to identify any impurity above 0.1 percent, okay, whatever the particular case is.

So as you mentioned, okay, SynCores didn't do -- find the NDMA, NDEA, because which is a much lower level impurities, which ICH guidelines, FDA guidelines didn't require that.

And you just measure, okay, even after 2018, Novartis noticed ZHP, say that is a known impurity, which could be -- which might be.

So we learned about the NDMA and NDEA, those GTI impurity, in the valsartan process after we go through so many years, we learned more and more, and we finally discover that is the case.

So I don't know whether your question is -- your comments is correct or not, I wouldn't comment. That's my response.

Q. I went through with you a few moments ago, the EMEA standards going back to 2007, which said that with

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nitrosamines, the threshold approach doesn't apply.
Do you remember that?
A. Yes, I remember that. Nitrosamine compound.
Q. And that was established as of 2007, years before you were developing the zinc chloride process, correct?
A. Yes, that's correct.
Q. So if -- if you had actually identified the NDMA impurity, you then would have had to work to try to determine whether there was any acceptable level of NDMA in the valsartan at that time. You would have had to actually explore that and analyze it, correct?
MR. BALL: Objection. Vague.
THE WITNESS: You know, the document that you just show me is European, you know, document. Okay. But you know what? Our process is also applied by the

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EDQM. So you're right, there's many, many guidelines, documents, even some forecasts out there.
But you know what? The process is approved by the EDQM.
BY MR. SLATER:
Q. Just to be clear, you agree with me that the TTC approach could not have been applied if you had actually identified the NDMA impurity, correct?
A. That's not correct.
MR. BALL: Objection.
THE WITNESS: Rick, go ahead.
MR. BALL: Objection. Mischaracterizes earlier testimony.
Go ahead, Eric.
THE WITNESS: You know, the TTC approach, these days, okay, it's been changing back and forth, as we discussed with FDA and EDQM. You confuse me there, okay.
Even nowadays we using the

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TTC as the limit setting for the -- for the potential genotoxic impurities.
As for the nitrosamines series, what's the approach to set limits, whether it's using TTC or other ppb, or other things, okay, I have to double confirm. But I disagree with you.
BY MR. SLATER:
Q. Well, you're certainly not using the TTC approach with regard to nitrosamine impurities, correct?
A. That's not correct. Because as you know, okay, the guidelines, the ICH, you know, guidelines, they started from Q3, Q7, Q9, M3, M7, M9. It's also improved or modified as we gain more and more knowledge.
Now the question you asked me whether the nitrosamine should not use the TTC to set the limits, I think I better draft a letter to ask the FDA whether this has been changed or not.

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Okay. What -- how should we set the TTC -- set the limits.
Q. Well, according to the EMEA, it says risk assessment of members of such groups, including nitrosamines, requires compound-specific toxicity data. It's supposed to be done item by item, isn't it? Or do you not know?
A. Adam, that's just giving a level -- because all those so-called potential genotoxic impurities, they giving high the dose to the animals. Then they extrapolate the data into humans. It's all for reference. There's no human data for that.
Q. Based on the information available to ZHP, ZHP evaluated the risk and determined it needed to quarantine and recall all of the valsartan that it had distributed in the United States, correct?
A. Yes, as far as we understand. Even at that time, we suspect that unknown peak is NDMA and

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NDEA, you know, from protecting the patient's interest, ZHP take the, you know, proactive step to recall all those materials on the market.

Q. You're aware --

A. Following with investigation to further confirm, okay, that's the, you know, GTI impurity that existed in the valsartan, and all other sartans as well.

Q. You're aware that ZHP attempted to get the FDA to approve much higher levels than what the FDA eventually set as the limitation? You are aware of that?

MR. BALL: Objection. Outside the scope.

THE WITNESS: Adam, could you give me more details? I don't know --

BY MR. SLATER:

Q. Well, did ZHP advocate for a level of 4.7 ppm to be acceptable in the valsartan?

A. Adam, I wouldn't even --

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MR. BALL: Objection. Hold on.

Objection. Outside the scope.

MR. SLATER: This isn't outside the scope because --

MR. BALL: Sure, it is.

MR. SLATER: It goes to the evaluation conducted by ZHP with regard to the health --

MR. BALL: That's not what you're asking him. You're asking what they told FDA. You're not asking what their evaluation was.

MR. SLATER: This -- of course it is. This is what the outcome of their evaluation was, to tell the FDA they thought this was safe. So of course --

MR. BALL: So, Adam, ask him a question about that. Don't ask him what he told the FDA -- what he didn't tell the FDA.

MR. SLATER: With all due

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respect, I think my question is appropriate.

MR. BALL: Okay. And that's totally fine. I'm just making my objection. The court can totally disagree with me.

BY MR. SLATER:

Q. Are you aware of the levels in ppm that ZHP advocated to the FDA as being safe for the NDMA-contaminated valsartan?

A. Adam, talking to FDA is not part of the job of SynCores. We do not participate. Only do research, provide scientific data.

Q. When ZHP advocated those levels, did they do so based on a health and safety evaluation or did they do so based on a commercial analysis wanting to sell the pills that it had manufactured?

MR. BALL: Objection. Beyond the scope.

THE WITNESS: Adam, that's -- let me just rephrase

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that, okay.

Pharmaceutical business is heavily regulated, okay. That's why ZHP might have to talk to FDA, gets approval, okay.

That's a continuous, you know, improving process, to make sure the drug sold on the market are safe for patients.

BY MR. SLATER:

Q. Was ZHP surprised to learn in 2018 -- I'll withdraw that, actually.

If a proper risk assessment had been performed, SynCores would have evaluated whether or to what extent DMF was decomposing to yield DMA, otherwise known as dimethylamine, as part of the zinc chloride process, correct?

MR. BALL: Objection. Asked and answered.

THE WITNESS: Adam, I think I answered the question several times already.

MR. BALL: Go ahead and

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answer it again if you can, Eric -- Dr. Gu.

THE WITNESS: Okay. SynCores did what we can, okay, following the ICH guidelines, GMP guidelines, to study valsartan at that time in 2011.

I think we did, you know, whatever we can, okay, to assess, you know -- to make sure that we make the better quality valsartan at the time.

BY MR. SLATER:

Q. In retrospect, as you sit here now, you would agree with me that the scientific analysis of potential impurities was inadequate. You would agree with that now, looking back, correct?

A. Looking back, from the standpoint of now, okay, as we have more advanced -- you know, much more sensitive instrument, we get more and more knowledge about the process and genotoxic

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impurity, yes. The answer is yes, under that preconditions.

That's why, as I said, the ICH guideline, the GMP are always changing and modifying as we gain more and more scientific knowledge. It's called cGMP guidelines. It's always current.

So that's why the ICH guideline always, you know, updating, gaining more and more sections.

Q. Let's go through that. Number one, GC-MS, otherwise known as gas chromatography mass spectometry, was a known available technology in 2011, correct?

A. GC-MS is the -- is the technology, sure, it existed back in 2011, yes.

Q. Did ZHP actually use GC-MS as part of any of its evaluations of any of the drugs it was manufacturing back in 2011? Do you know?

A. I -- I didn't know, because

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I wasn't there. But I know in 2011, GC-MS is not widely used in industry. We using GC a lot, okay, to detect in the reduced solvent those unknown peaks.

SynCores at that time does not have GC-MS.

Q. You don't know if ZHP did?

A. I didn't ask. I'm not sure.

Q. It was known in 2011 that GC-MS was best way to identify nitrosamine impurities, correct?

MR. BALL: Objection. Vague. And calls for an expert opinion.

THE WITNESS: Adam, I cannot tell you that, because at 2011, okay -- 2011, no one knows there's NDMA in the, you know -- many product. For the valsartan, we didn't know it's in there. So I wouldn't be speculating. GC-MS is the better -- you know, the best equipment to detect NDMA and NDEA.

BY MR. SLATER:

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Q. It was known that GC-MS was the best equipment to identify NDEA and NDMA. That was known in 2011, correct?

MR. BALL: Objection. Calls for expert opinion.

THE WITNESS: Adam, I don't know. Because GC and GC-MS are two different type of equipment. GC-MS is designed to detect, you know, qualifying those low level impurities much better than the GC. That's all I can say.

BY MR. SLATER:

Q. I'll try it differently. Maybe this will help.

You would agree with me that ZHP knew by 2011 that mass spectometry was the best way to identify nitrosamines, correct?

A. That's not correct. ZHP didn't know.

Q. Did SynCores know that?

A. SynCores does not know either. We only have GC at SynCores at

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that time.
As I said again, okay, industrywise, even the FDA, EDQM, they all know GC is the popular equipment in the, you know -- in the pharmaceutical industries.
Q. Have there been other times where at SynCores you've developed a lab scale process where there was a risk to create nitrosamines where you didn't try to test to see if that impurity was being created or not? Is there another example you can give me?
A. What examples? Adam, I'm confused. What example are we talking about? SynCores different product? What?
Q. Is there a time where SynCores developed a process to develop or to manufacture a drug product, thought that nitrosamine impurities were potential outputs, and didn't try to test to determine whether there were actually nitrosamine impurities?

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MR. BALL: Objection. Outside the scope.
THE WITNESS: Adam, the answer is no.
BY MR. SLATER:
Q. That would be reckless, right?
A. You know --
MR. BALL: Objection. Mischaracterizes his testimony.
THE WITNESS: Why you want to do that?
BY MR. SLATER:
Q. If SynCores or ZHP knew that a nitrosamine could potentially be created by the manufacturing process, it would have been reckless not to try to test to identify that impurity, right?
MR. BALL: Objection. Compound, and mischaracterizes his testimony, and it's been asked and answered.
THE WITNESS: Okay. Adam, if we know, okay, if we suspect,

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okay, we have to do the thorough studies, do the entire risk assessment to get that out of the process, get that impurity out -- under control in the final drug, APIs.
BY MR. SLATER:
Q. Are you aware that Novartis detected the NDMA peak with gas chromatography?
A. No. As I said again, Novartis use GC to give you -- they suspect, okay. That's a unknown peak. They labeled it as unknown peak.
Q. And then Novartis took the next step and investigated that peak and learned that it was likely NDMA, correct?
A. Adam, we talk about this just a while ago. Novartis, you know, suspect a peak, which labeled as unknown peak. Then they send this issues to the external professional laboratories. The results they give out is also this highly suspect that could be the peak.

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And then they noticed the ZHP. ZHP, the scientists, the developers, specified a method and finalized, confirmed, okay, that's the structure, is the NDMA. That's my side of -- my version of how this happened.
Q. Novartis notified ZHP of this suspicious peak and then when ZHP did not investigate it further, Novartis went to Solvias, the independent lab, and Solvias, the independent lab, performed GC-MS and identified it as likely NDMA. That's what occurred, correct?
MR. BALL: Objection. Foundation.
THE WITNESS: Adam, I think I told you my version of story several times, okay.
Novartis noticed us that could be a suspect peak. They labeled as unknown peak, okay. ZHP, when we learned that, okay, we did our study to finally determine that's the NDMA.

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We developed a specific method to detect that.
MR. BALL: So Adam, we've gone almost 80 minutes. I'm happy to let you continue this line of questioning if you want or we can take a break.
MR. SLATER: It's up to you. I can keep going.
MR. BALL: Okay. Go ahead. Keep going, as long as Dr. Gu is fine.
THE WITNESS: Why don't we take ten minutes off. I'm hungry.
MR. BALL: Fair enough.
THE VIDEOGRAPHER: The time right now is 11:31 a.m. We're now off the record.
(Short break.)
THE VIDEOGRAPHER: The time right now is 11:44 a.m. We are back on the record.
BY MR. SLATER:
Q. Just to reorient ourselves,

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Novartis noted a peak that was concerning to it on regular gas chromatography, correct?
A. Novartis discover -- they call it unknown peaks.
Q. You told me earlier, and I think -- rephrase.
I think you agreed with me earlier, risk assessment occurs for the lifecycle of the product, correct?
A. Risk assessment, if you're looking at the ICH M7, okay, risk assessment is -- usually applies to new product, okay.
For the commercialized product being approved by the FDA and EDQM, they are not request to going back to look for -- looking for the -- how should I say it? Okay.
Just directly to your question, you know, part of quality should be continuously monitored.
Q. And one of the things that must be monitored is unknown peaks that

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may show up on gas chromatography, correct?
A. Yeah. Once you find out there is unknown peak, they should do the -- you know, try to investigate it, what's the unknown peak, you know.
Q. The unknown peak that was seen by Novartis was fully available to ZHP as well, correct?
MR. BALL: Objection.
THE WITNESS: I wouldn't comment on that.
Rick, go ahead.
MR. BALL: No, that's fine. Go ahead.
THE WITNESS: I wouldn't comment on that. That's the -- unknown peak, maybe it was communicated to ZHP quality units.
BY MR. SLATER:
Q. The quote-unquote unknown peak that Novartis saw was actually a peak that had been repeating from the beginning when ZHP began to manufacture

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valsartan with the zinc chloride process, correct?
A. Adam, let me -- let me tell you what I know, okay, because I didn't know there is, you know, unknown peak was discovered after 2016 or so. I wouldn't comment on that, because I'm not in the quality unit.
Q. Well, in terms of ZHP's evaluation and knowledge of the risk of the creation of nitrosamines, an important part of that evaluation would have been evaluation of unknown peaks, correct?
A. Adam, I didn't quite comprehend your questions.
Q. ZHP was responsible to evaluate any unknown peaks seen with its valsartan, correct?
MR. BALL: Objection. Vague.
THE WITNESS: ZHP were doing investigations for those unknown peaks as ongoing efforts.

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BY MR. SLATER:
Q. The peak that Novartis saw, had ZHP evaluated that peak previous to that?
A. Previous to what?
Q. To when Novartis brought it to ZHP's attention?
A. I don't know, because as I said, Adam, I'm not in the quality unit. I'm don't know the time frame, or exactly the time, what was happening that time.
Q. ZHP certainly had an independent duty to be continuously monitoring the product quality, including looking for unknown peaks or aberrant peaks, correct?
MR. BALL: Objection. Vague. Calls for a legal conclusion. I think.
THE WITNESS: Adam -- Rick, can I answer the question?
MR. BALL: Yeah, please answer.
THE WITNESS: As you know,

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the pharmaceutical companies did do the annual review, quality review every year. And they file with the FDA or EDQM, those regulatory bodies, okay.
BY MR. SLATER:
Q. Did ZHP notify the FDA or the European authority there was an unknown peak showing up on gas chromatography that ZHP was not further evaluating?
MR. BALL: Objection. Mischaracterizes the earlier testimony, and foundation.
THE WITNESS: You know, Adam, I'm not in the quality unit or QA or regulatory department. They communicate with EDQM and FDA on a yearly basis about those commercial product, okay.
SynCores are not involved in that.
BY MR. SLATER:
Q. We were talking about

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Novartis a few minutes ago. And let me ask -- rephrase.
Speaking of Novartis, can you tell me why it was that Novartis noticed the NDMA peak and then further evaluated it through an independent lab and confirmed it was NDMA before ZHP did?
MR. BALL: Objection. Mischaracterizes his earlier testimony.
Go ahead -- or go ahead, Eric, Dr. Gu.
THE WITNESS: Okay. Novartis they discovered an unknown peak, okay. They turn over this question to the contract laboratory to do further studies.
I'm sure, okay -- I wouldn't speak for my QC and quality units. I'm sure they also investigating those, you know, unknown peaks as their routine work.
BY MR. SLATER:
Q. If I understand what you

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said, you were saying that you were sure that the quality assurance and qualify control units were evaluating those peaks independently already?
A. I'm sorry, Adam. I didn't --
Q. Did you testify that it's your understanding that the QA and QC departments at ZHP were independently evaluating that unknown peak that Novartis found on their own before Novartis came to them?
A. You know, they -- because Novartis is one of our clients, so I'm sure they keep talking to each other. They have to set the limits which meets the FDA also as well as the Novartis, you know, specifications.
When it seems like unknown peak was discovered, I'm sure they communicated with each other. They do all -- they all doing their own independent research on those unknown peaks.

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Q. Since ZHP was the manufacturer, you would think that ZHP should have been the one to notice the unknown peak and identify what it was before one of its customers had to bring it to its attention, right?

A. Adam, how can I answer this question. Because each company doing their own studies, okay. What you miss, other people may catch it. Okay. That's why in the scientific community, or even clients in the supplies, quality is always talking to each other, to share information, to discuss, to discover more and more about the product.

There's no such question, should or should not, okay. It's scientific issues.

As I mentioned earlier, for those NDMA, NDEA, those lower level below ppm level, you know, impurities, it was not -- it was not so easy to detect. You have to develop a specific method in order to discover, qualify, and quantify

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those impurity.

That's a -- you know, it's quite a challenging work, especially for those very lower limit impurities, or unknown peaks.

MR. SLATER: My internet connection got a little funky there. Michelle, could you, if you have a moment, read me that answer back because I was -- all I was hearing was mechanical sounds because of my internet connection.

MR. BALL: Essentially what he was saying, he was channelling Mr. Roboto.

MR. SLATER: That's pretty much what I was getting. It was a good song.

(Whereupon, the court reporter read back the requested portion of testimony.)

BY MR. SLATER:

Q. Are you aware that ZHP actually certified in the DMF that there

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were no n-nitroso impurities in the valsartan manufactured with the zinc chloride process?

MR. BALL: Objection. Vague. And outside the scope.

THE WITNESS: Adam, DMF filing is, you know, regulatory department's, you know, job.

SynCores or me personally don't get involved into the DMF filings or regulatory communication with EDQM or FDA. I couldn't answer your questions.

BY MR. SLATER:

Q. As a matter of risk assessment, the only way you could state with certainty that there were no n-nitroso impurities in the valsartan would be to test with GC-MS method, correct?

MR. BALL: Objection. Calls for expert testimony.

THE WITNESS: The only way you can do that, first of all, you

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would know or you would suspect that there were such impurities.

Second of all, you need the high resolution mass to have the capability to detect such lower level impurity.

Third of all, you have to develop a method specifically to detect the impurity without any interferes with the other substance in the matrix.

So it's quite a challenging work.

BY MR. SLATER:

Q. Okay. Once Novartis told ZHP about this suspicious peak, ZHP was able to confirm it was NDMA within days, right?

A. I don't know exactly how long that takes.

THE WITNESS: Rick, you have something to say?

BY MR. SLATER:

Q. Yeah, let me -- I'll re-ask

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it again because I paused. Not your fault. I just paused before you started to talk.

When ZHP was notified by Novartis of this potential NDMA peak, ZHP was able to confirm it was NDMA very quickly, right?

MR. BALL: Objection. Vague.

THE WITNESS: Adam, okay, I think when we, you know, noticed that there's an unknown peak, you know, that may be that GTI, ZHP, you know, utilized many resources, including external -- you know, external contract laboratories, and also internally, you know, many people work on that.

I don't know how quickly is that. I did not keep the timestamps for that.

BY MR. SLATER:

Q. Five or six days, does that sound correct to you? June 5th to

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June 11th?

A. I don't know exactly. But you know, I think about a week or so, because once you have the lead, okay, you know, what you're looking for, and you can get the reference data material from the market, and you have the equipment to do such a job, and you also use different contract labs, because ZHP committed many resources to find out what's -- what the unknown peaks are.

So it's -- there are -- it's great efforts, okay, to get that turned around really quickly. I don't know how long that takes. I don't have a timestamp.

But as you said -- you mentioned, maybe you are right, within a week or so. But within a week, so they did so many experiments, so many people gets involved, okay.

You know what they're looking for. That's a different -- that's a whole different stories.

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Q. Well, Novartis did not understand the manufacturing process for the valsartan as well as ZHP did, right? You would agree, ZHP understood the process better, right?

MR. BALL: Objection. Calls for speculation.

THE WITNESS: Okay. Adam, because we provide the process description to the Novartis.

To some extent, I think, you know, yes, of course, ZHP knows a little more. But I'm sure Novartis knows a lot too.

BY MR. SLATER:

Q. Are you aware that on June 9, 2018, Novartis asked ZHP if ZHP was destroying the excess azide with sodium nitrite?

A. I'm sorry. I didn't quite -- I'm sorry, Adam. Could you say it again?

Q. Sure. Are you aware -- are you aware that on June 9, 2018, Novartis

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asked ZHP if ZHP was eliminating the excess azide with the addition of sodium nitrite and was doing so in the presence of the valsartan product? Are you aware that Novartis had to ask that question to find that information out?

A. I didn't know, because, you know, Novartis asked ZHP about that. That's called quenching the excess sodium azide, which is quite a toxic materials.

Q. That's when the nitrous acid from the sodium nitrite reacted with the DMA and formed the NDMA, correct?

A. That was later, when we did the full scope of the risk assessment. We do the mechanistic studies of how this was formed. Then we later find out that's the case.

Q. So I come back to my original question.

Shouldn't ZHP have noted the unknown peak and done this whole investigation on its own before any of its customers had to bring this to its

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attention?
MR. BALL: Objection. Calls for speculation. Mischaracterizes his previous testimony.
THE WITNESS: Adam, do I have to answer the question?
MR. BALL: Yes, you need to answer.
THE WITNESS: Okay. Adam, as I mentioned earlier, there is no should or should not. It's a scientific question. It's quite a challenging question.
In the scientific communities, okay, we communicate with each other. We share information. We share technology. We share the method. I wouldn't, you know, speculating who should or who should not discover this issue first.
BY MR. SLATER:
Q. Well, this product was not some product that the scientific

Page 227

community collectively was selling. This was a product ZHP was selling and profiting from, correct?
MR. BALL: Objection. Outside the scope and compound.
THE WITNESS: Well, actually, Adam, Novartis is the originators. They make the product much longer than ZHP has been.
BY MR. SLATER:
Q. Who did?
A. Novartis.
Q. You're saying Novartis manufactured valsartan with the zinc chloride process?
A. I don't know what process they use, but they make the valsartan much longer than the ZHP.
Q. You're not aware that ZHP was continually trying to increase the yield, and that's how they ended up having SynCores develop the zinc chloride process, by a different process than what

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Novartis had been doing?
A. I'm not aware of that, because our -- SynCores is developing a method with the clients to making better quality materials, lower waste, and much safer process.
Q. Well, the Novartis process to manufacture Diovan worked fine, right?
MR. BALL: Objection.
BY MR. SLATER:
Q. Let me ask it again.
The Novartis process to manufacture Diovan, the original brand name, that worked fine, right?
MR. BALL: Objection. Speculation. And vague.
THE WITNESS: I don't know. I don't know what you mean by fine, okay.
BY MR. SLATER:
Q. Well, it was approved. They sold Diovan. There was never a recall for nitrosamines being in the Diovan. Those are true statements, correct?

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MR. BALL: Objection. Compound.
THE WITNESS: Adam, could you -- could you -- forgive me, okay. Could you repeat that question again?
So they make the Diovan -- actually, we're talking about valsartan compound, right? Diovan is the commercial name for the compound -- for the drug?
BY MR. SLATER:
Q. Diovan was the brand name.
A. Brand name. We're talking about valsartan API, right?
Q. Correct.
A. Okay.
Q. When Novartis was manufacturing and selling Diovan, it was not contaminated with nitrosamines, correct?
MR. BALL: Objection. Calls for speculation.
THE WITNESS: Adam, I don't

Page 230

know. I haven't tested Novartis compounds yet.
BY MR. SLATER:
Q. When you were optimizing the process to manufacture valsartan, did you look into how was valsartan manufactured previously when it was brand?
A. That's the Novartis process. We search the literature, patents, everything, okay, there's many versions of the process out there.
Q. Did any of those versions include the use of DMF?
A. In public information?
Q. Any of the information that you had access to.
A. Well, we only had access to public information. We could not access other company's trade secrets. So I will not answer that question.
Q. Well, from everything you saw, you never saw use of DMF by Novartis, right?
MR. BALL: Objection.

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Vague.
THE WITNESS: Adam, I don't know. I don't know how Novartis make that.
BY MR. SLATER:
Q. Why was it that Novartis needed to bring the unknown peak -- well, rephrase. Let me ask it differently.
Why was it that Novartis had to bring the NDMA peak to the attention of ZHP? Why didn't ZHP discover it first? As a matter of factual information, why was that?
MR. BALL: Objection.
THE WITNESS: Rick, go ahead.
MR. BALL: Calls for speculation.
Go ahead.
THE WITNESS: Adam, as I said, again, okay, in the past, Novartis bring this to our attention, label it as an unknown peak, which suspect could be that.

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BY MR. SLATER:
Q. But my question is why didn't ZHP figure this out first? Why did it take till Novartis brought it to ZHP's attention?
MR. BALL: Objection. Calls for speculation. To the degree that you can answer, please do, Eric.
THE WITNESS: Okay. I think we discussed that in the earlier, okay.
This is -- I said it's a lower level impurity. It is an unknown peak, initially labeled as -- you know, as we have that much knowledge about it.
As the time passing by, doing more and more research, then we finally, okay, identify this as the NDMA.
BY MR. SLATER:
Q. You would agree with me that as a matter of risk assessment and

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evaluation for impurities, ZHP should have evaluated that NDMA peak as soon as ZHP saw it, correct?
MR. BALL: Objection. Vague. Foundation.
THE WITNESS: Adam, we talk about should have or should not. I don't know how to answer you this question. I think I answered this question before.
BY MR. SLATER:
Q. As a matter of current good manufacturing practices, when ZHP saw that NDMA peak, it should have investigated it and identified it as soon as it saw it, right?
MR. BALL: Objection. Foundation.
THE WITNESS: Adam, that was labeled as unknown peaks, okay.
BY MR. SLATER:
Q. Well, an unknown in a drug that's going to be taken by human beings has a potential risk, right?

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A. Adam, if you look at the many other drug as well, the FDA, ICH guideline clearly specifies if it's below 0.1 percent, you don't have to qualify, quantify. If it's above 0.1 percent, you have to know the structures.

As we all know, if you go in further, okay, the drug substance is, let's say, 99.9 percent pure, there are still many so-called unknown peaks in there. It depends on the qualitative limits.

Let's say for a compound, the unknown peak is 0.05 percent, you don't have to do structure analysis. You don't have to know what it is. That's the current -- even today, that's a current FDA guidelines.

You know, in this case, we are talking about the NDMA, which is much lower than 0.05 percent. And that's why this is so difficult, okay, to making a drug and know all the so-called unknown peaks in the drug substance or drug

Page 235

product.

It's our efforts in the industry continuously to advance and improve ourselves, we try to gain an understanding of all those unknown peaks in any drug substance. But that's almost impossible job for this time -- at this time now. But we will eventually get there.

Q. I didn't mean to interrupt you. Were you done?

A. Yeah, I'm done.

Q. Why did Novartis figure out the importance of DMF in this whole situation before ZHP did?

MR. BALL: Objection. Calls for speculation.

THE WITNESS: I don't know.

MR. BALL: Mischaracterizes earlier testimony.

THE WITNESS: Rick, okay, can I answer now?

MR. BALL: Yes, please.

THE WITNESS: I don't know

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who discovered this, you know, phenomenon first, okay, Novartis or ZHP. I wouldn't speculate on that.

BY MR. SLATER:

Q. Well, you know for a fact that Novartis was asking questions about DMF of ZHP before ZHP ever considered DMF as being part of the process leading to the NDMA peak and the presence of NDMA in the valsartan, correct? That's a fact, right?

MR. BALL: Objection. Foundation.

THE WITNESS: Adam, I didn't get involved with a communication or with Novartis. I do not know. But as far as we know, okay, we did the risk assessment. We found out, okay, that could be in the one that could pass, that form the NDMA.

BY MR. SLATER:

Q. What I'm trying to get at

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is, what was it about ZHP's evaluation that caused it to not connect DMF to that, quote, unknown peak that turned out to be NDMA until after Novartis started questioning the use of DMF in the context of that peak? I'm asking, why did ZHP not figure this out first? Why did it need Novartis to take it there?

MR. BALL: Objection. Asked and answered. Foundation.

THE WITNESS: Adam, as I said, I am not getting involved with communication with Novartis. That is the quality responsibility.

As to your question, why ZHP did not find out before Novartis, I do not know.

BY MR. SLATER:

Q. Wouldn't the answer be that the quality risk assessment was inadequate by ZHP?

MR. BALL: Objection. Calls for opinion and expert testimony,

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and mischaracterizes his testimony.

THE WITNESS: We keep going there. Adam, can we skip that?

MR. BALL: Go ahead and answer again, Dr. Gu.

THE WITNESS: I just disagree with Adam. I said it many, many times already, okay. This is -- as the technology advances, as the, you know, detection equipment gets -- advances, we gain more and more knowledge about those drug substance, all those unknown peaks or impurities in the compounds. It takes time.

BY MR. SLATER:

Q. Speaking for ZHP in this deposition, are you thankful that Novartis figured out that this unknown peak needed to be investigated so that the NDMA could be discovered?

MR. BALL: Objection.

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THE WITNESS: You know what, Adam, we also share our information with Novartis as well.

Yes, we were appreciative, okay, the technology and advancement, people discover more and more.

You know, if you're asking me whether we thankful, sure, if somebody help me to improve the drug safety, I want to be thankful. So are other companies as well.

MR. SLATER: Cheryll let's go back to Exhibit 228, if we could, if you're still there. I know you're still there. I'm just kidding.

MR. BALL: I'm not being rude. I'm just getting a bottle of water. I'll be right back. Go ahead and go. I can still hear you.

MR. SLATER: I've got to

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read something.

Cheryll, let's go to Page 12 of 28 on this. And we're back in, just for the record, Exhibit 228, the letter from ZHP to the European agencies.

Yeah, good luck with the turning of the document.

BY MR. SLATER:

Q. I'm looking now at -- actually, did I say -- what page did I say? 12. Let me go back to that.

A. Adam, can you expand the document? It's so -- the letter so small.

MR. BALL: Yeah, Adam, I can barely read this. If we can enlarge the screen.

MR. SLATER: It's fine. I'm just going to figure this out.

Yeah, go to Page, actually, Cheryll, 12, if you're on it. Yeah, good. And you can expand it. I'm looking at Box B, so the

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top box I'm not focusing on if you need more space. And I'm looking at the box on the left.

BY MR. SLATER:

Q. Looking at Box 4B in this document, this is per the agencies, the European agencies. It says that, "The inspection team reviewed the documentation for complaint CC-18004, received on May 22nd, 2018, from customer Novartis in Ireland. Unknown peak detected on 16 batches of valsartan."

Do you see that?

A. Yeah, I see that.

Q. And as we know now, that unknown peak -- unknown peak represented NDMA, correct?

A. I wasn't involved. Probably that's the unknown peak, yep.

Q. And then in B1, little single i, it says, "They provided typical chromatogram of valsartan (GC residual solvents) used to identify the unknown peaks and to provide an answer to

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Novartis's complaint, was not related to any of the batches concerned by the complaint, but was related to complaint investigations requested by Sun Pharmaceuticals in November 2016."

I want to stop there. Are you aware of the fact that Sun Pharmaceuticals was complaining of unknown peaks in November of 2016?

A. I'm not in the QC or QA department. I'm not aware of that.

Q. Then according to ii, it says, "After being asked why no direct comparison of the unknown peaks observed by Novartis and their own GC chromatograms had been made, the company stated that they were not in possession of the customer's method at the time of the complaint. However, after a review of GC audit trails, it became evident that the company had already obtained the Novartis method in December of 2017.

"From further checks on the communications between the company and

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Novartis, it became evident that Novartis had shared the GC-FID method with Z. Huahai already in July of 2017 as a means of supporting investigations on unknown peaks."

So I'm going stop there.

So are you aware -- or were you aware before now that as of 2017, Novartis's method to evaluate these peaks was already in ZHP's possession? Did you not know that before now?

A. I'm not knowing that before now. And also, be very specific, okay. You look in the document. They only share the GC-FID method with ZHP. It's very -- clearly states in there. That's only the -- that's the observation of the European EDQM inspection, right?

MR. SLATER: Let's go, Cheryll, back to Page 10, Box Number 3.

THE WITNESS: Page 10.

MR. SLATER: Perfect.

BY MR. SLATER:

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Q. This says, "As part of the root cause analysis" -- rephrase.

Looking again here at the letter from ZHP to the European agencies, November 14, 2018, Box 3, first is the observation by the European regulatory. And it states as follows:

"As part of the root cause analysis of the NDMA/NDEA contamination, the development of the 2011/2012 revised valsartan manufacturing process (introduction of the zinc chloride process) was reviewed and the following observations were made."

Are you following where I'm reading, correct?

A. Yeah, I'm following.

Q. Let's go now to the box --

MR. SLATER: You can scroll down, Cheryll. Thank you.

BY MR. SLATER:

Q. And A says, "The modified process was developed by the Huahai Pharmaceuticals research and development

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facility, Shanghai SynCores Technologies Inc. Contrary to what the company stated in their retrospective analysis of the process change, the core principles of ICH Q8, Q9, and Q10 were not considered and potential impurity profiles and associated risks were not addressed by the R&D laboratory."

Let's stop there now. The R&D laboratory, again, is SynCores, your company, correct?

A. Yes.

Q. And you would agree that the core principles of ICH Q8, Q9, and Q10 were not considered in SynCores' evaluation, correct?

A. You know what, Adam, because this observation was done -- am I right, 2018 sometime?

Q. Yes.

A. Okay. Yes, at 2018 looking back to the 2010 or 2011, you can make all those comments.

Don't forget, okay, this

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process, the part was approved by EDQM as well. Between 2011 and 2012, and 2018, EDQM, they have inspect Huahai many times as well, okay.

Third of all, I'm not sure if the ICH, Q8, Q9, Q10 was out there in 2010 or '11.

So you cannot look in the back mirror and try to finger pointing at people what they do not know.

But this document looks interesting, okay. Keep that in mind, the entire process was approved by the same agency.

Q. This says that, "As the result of what we just talked about, potential impurity profiles and associated risks were not addressed by the research and development laboratory," which again is SynCores.

And, again, looking back on that now, and even in 2018, that's a correct statement, right?

A. Yeah, looking back, now,

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yes, you can say that.

Q. Looking now at Letter B, it states, "Furthermore, no risk assessment was made by the company to identify the impurities related to the new solvent used (DMF) when implementing the process proposed by research and development."

Do you see that?

A. I see that.

Q. And this is speaking to ZHP not performing a risk assessment to identify the impurities related to the new solvent used, which was DMF. That's a correct statement, ZHP did no risk assessment on the DMF, correct?

A. I disagree with that, because the 2010 or 2011, we screened all -- many different kind of solvent, including DMF, okay.

We believe the DMF was, you know, very stable. It's a good solvent to use. It produces better quality material of valsartan at that time. But today, now, once they find out all those

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information, as the risk assessment has been done, it's easy to say, because looking back into 2011.

Q. Are you testifying that ZHP performed a risk assessment to identify the impurities related to DMF?

A. You know, Adam, as we talk about it, okay, DMF is a commonly known solvent. You know, even actually what you're talking about, we use tons of DMF, okay. Decompose into, let's say, ppm levels. I don't know if you have any idea about the scale differences, okay.

So when you're talking about something stable and something is not stable, you have to put it on the scale.

Q. I'll try again.

Are you saying that ZHP actually performed a risk assessment to identify the impurities related to the use of DMF when implementing the zinc chloride process? Are you saying that ZHP did that risk assessment?

A. I can --

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MR. BALL: Objection. Asked and answered.

THE WITNESS: Rick, can I answer now?

MR. BALL: Yes.

THE WITNESS: Okay. I don't know about ZHP, but for SynCores we did a solvent screening for many different solvents, including MMP, MTBE, dioxides, many solvents, okay. That's all I can tell you.

We did the, you know, solvent screening, or risk assessment for the selection of a solvent.

BY MR. SLATER:

Q. You've not seen any documents or been told by any person in preparing for this deposition that ZHP performed a risk assessment to identify the impurities related to the use of DMF, correct?

A. That's, I don't know what to

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answer. What's correct? Okay. I don't see any document. Just use the DMF solvent risk assessment in the past.

The answer is I didn't see any documents. But the solvent usage for the researchers, we just basically, you know, look into solvents, stability, boiling points, and, you know, see if it's suitable for the process.

But, you know, at the end, okay, we have to analyze the final product, the valsartan in this case, see which -- the quality of the valsartan is to remain better quality than the -- or equal or better quality than the, you know, original process. We're talking about process optimization right here.

Q. What you did not look at was potential impurities that could result from the use of DMF in the process. That was something that you did not look at, correct?

MR. BALL: Objection. Asked and answered.

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THE WITNESS: Adam, I'm confused.

We look at everything we can look, okay, based on the knowledge base at the time. And we follow all those GMP guidelines, ICH guidelines. And we make better quality materials and getting approved from the FDA and EDQM.

BY MR. SLATER:

Q. Is there -- well, let me ask you this.

Are you saying that valsartan contaminated with NDMA was better quality than valsartan contaminated with NDMA and NDEA, which was the fact with the valsartan manufactured by the sodium nitrite quenching process? Is that the point that you're making?

MR. BALL: Objection. Mischaracterizes his earlier testimony.

THE WITNESS: Adam, put your

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question into content, okay.

That was 2011. We didn't know. If we know that, that wouldn't happen.

MR. SLATER: Cheryll, I'm going to put up a few more documents. We may come back to this. But you can take it down for now.

What I want to go to now is some of the ICH standards. I want to start with the ICH standard titled "Pharmaceutical Development Q8, Revision 2," dated August 2009.

MS. CALDERON: Give me one second.

MR. SLATER: Yeah, no problem.

Okay. Thank you, Cheryll.

MR. BALL: Excuse me.

MR. SLATER: I take that as validation.

Looking on the screen --

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what exhibit is this now? I'm sorry. I can never keep track of exhibit numbers.

MS. CALDERON: 229.

(Document marked for identification as Exhibit ZHP-229.)

THE WITNESS: 229.

BY MR. SLATER:

Q. Looking now on the screen at Exhibit 229, this is ICH Standard Q8 titled "Pharmaceutical Development" dated 2009.

Do you see that?

A. Yes.

Q. During your prior testimony, you questioned whether or not the ICH guidelines that were cited by the European authorities had been in effect when the valsartan zinc chloride process was being developed.

Do you remember you had mentioned that during your testimony?

A. Yeah.

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Q. So I'm showing you Q8. You can see that was in effect as of August of 2009.
You see that, correct?
A. That's Revision 2, yep.
MR. SLATER: Okay. Now, let's take that down and go to Q9, titled "Quality Risk Management" as Exhibit 230.
(Document marked for identification as Exhibit ZHP-230.)
MR. SLATER: When you get to it, Cheryll.
BY MR. SLATER:
Q. On the screen is Exhibit 230, titled "Quality Risk Management, Q9." You can see the date for that is November 9, 2005, correct?
A. Yes.
Q. So that also was in effect before 2010, correct?
A. Yes.
MR. SLATER: Now, let's go

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to Exhibit 231, which will be Q10, titled "Pharmaceutical Quality System."
(Document marked for identification as Exhibit ZHP-231.)
BY MR. SLATER:
Q. On the screen is Exhibit 231, titled "Pharmaceutical Quality System, Q10" dated June 4, 2008.
Do you see that?
A. I see it.
Q. This shows that this standard also was in effect before 2010, correct?
A. Yeah.
MR. SLATER: You can take that down.
Let's go now as Exhibit 232, let's go to a new document, which will be ZHP-01862672, the final cGMP inspection report from the European authorities.
(Document marked for

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identification as Exhibit ZHP-232.)
BY MR. SLATER:
Q. Exhibit 232 states at the very beginning that this is the final good manufacturing practices inspection report and states, "This final inspection report is issued after assessment of the company's answers and corrective action plan received on 14th of November 2018."
Do you see that?
A. Could you expand that a little bit? I see it -- I see it now. 14th November, '18, yeah.
Q. And this indicates as we read down --
MR. SLATER: If you can scroll down, Cheryll, about halfway down.
BY MR. SLATER:
Q. It confirms that the inspection date was September 10 to 13, 2018.
Do you see that?

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A. Yeah.
MR. SLATER: Then if you scroll down a little further, please, Cheryll.
BY MR. SLATER:
Q. It shows the names of the inspectors who actually attended. Let's go down to the next page, at top of the page.
MR. SLATER: You can scroll up a little bit.
BY MR. SLATER:
Q. It says, "Introduction, scope of inspection."
It says, "The joint EMA/EDQM inspection took place in the context of the EDQM CEP procedure and the Article 31 referral procedure, according to directive 2001/83/EC that was triggered after the detection of an impurity, NDMA, in the valsartan active substance supplied by several companies to manufacturers which produce some of the valsartan medicines available in the EU."

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Do you see that?
A. Mm-hmm. Yes, I see it.
MR. SLATER: Go to the next page, please, Cheryll, which is Page 3.
BY MR. SLATER:
Q. And towards the bottom is a list of key personnel that were met during the inspection.
Do you see where -- rephrase?
Looking now at Page 3 of this report, which is ZHP-1862674, is a list of key personnel from, I suppose, ZHP or its affiliates that met with the inspectors.
Do you see that?
A. I see it, yep.
Q. And the first two names, I just want to identify who they are for the record. The first one is Baohua Chen, president.
Do you see that?
A. Yes, I see it.

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MR. BALL: Adam, I'm guessing you're going to swing this back towards, at some point, to the actual 30(b)(6) topics.
MR. SLATER: I can introduce the foundation and some information about a document.
MR. BALL: All I did, Adam, is asking. Are you going to swing it back to the 30(b)(6) topics?
MR. SLATER: I think I'm right in the 30(b)(6) topics.
MR. BALL: No, you're not. You're asking about the inspection that was performed by the EDQM. Not within his 30(b)(6).
MR. SLATER: I think --
MR. BALL: In the final inspection report.
MR. SLATER: I'm sorry. I really do honestly think that this is appropriate. It's a document --
MR. BALL: I'm not

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instructing him not to answer. I'm asking, can you swing back to that, please?
MR. SLATER: Well, I think I'm in it.
MR. BALL: Okay. I don't. I'm not instructing him not to answer.
BY MR. SLATER:
Q. Okay. The first person -- rephrase.
On this list of key personnel met during the inspection by the European inspectors, it lists the first person is Baohua Chen, president, and that's the chairman of all of ZHP, correct?
A. Yes.
Q. And then Jun Du, it says executive vice president. And you know Mr. Du, correct?
A. Yes.
Q. I think you might have said earlier that you thought you attended

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these inspections; is that correct or --
A. I was -- when they was there, I just go to the site. And I know they -- and I was -- I was there, once. Yeah.
Q. I've scrolled through, and unless I missed it, I didn't see your name. But I'm just going to scroll through. I just want to make sure whether you were noted as being there. So I don't see you on that first page. Let's go to the second page.
MR. SLATER: And, Cheryll, if you can just slowly scroll through.
THE WITNESS: But you don't have to scroll through, because inspection usually the people join is the QA/QC manufacturing side.
MR. SLATER: Let's go then to -- I think you're there. You're on the right page. Scroll down a little bit further, please, Cheryll. Little more. Let's get

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the bottom. Perfect.
BY MR. SLATER:
Q. So now they're listing in the letter the major deficiencies they found. I would like -- and I would like to focus on a couple of them.
One, it says, "The investigation is conducted in the context of the NDMA/NDEA contamination of valsartan showed significant flaws."
Do you see that?
A. I see it. First observation, yes.
Q. This is listed as a major deficiency.
Do you see that?
A. I see it.
Q. Number 2 in the list of major deficiencies states, "The company's risk assessment performed in the context of the development/implementation of the optimized valsartan process conducted in July/August 2018 was not satisfactory. Moreover, the company did not identify

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the need to develop a control strategy to reduce new risks introduced with the optimized process."
Do you see that?
A. Right there, I see it, yes.
Q. And were you involved in the development of the optimized valsartan process?
A. We -- no. We did risk assessment. We didn't do optimized valsartan process.
MR. SLATER: Okay. Let's go now to the next page. Actually, it's a few pages further. Page 8, please. Yeah, let's go down a little more. I want to see more of the quality management section. Perfect. Thank you very much.
BY MR. SLATER:
Q. Looking now at the quality management section, this states in the second paragraph, "During the inspection the firm was requested to provide a summary of the events and the subsequent

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actions. The firm identified a 2011/2012 manufacturing process change as root cause for the NDMA contamination."
I want to stop there.
And that's consistent with your understanding, as well, correct, that the root cause for the NDMA contamination was the manufacturing process change to the zinc chloride process?
A. Yeah, that was after June '18. We did the risk assessment. We find that's the case.
Q. This says -- rephrase.
Continuing here in the second paragraph under quality management it says, "The process change was based on ZHP's Shanghai R&D laboratory (Shanghai SynCores Technologies, Inc.). The laboratory had been requested to perform process improvements studies because a number of issues had been identified within the TEA process, such as," and then it gives a list of issues.

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Do you see that?
A. Yes, I see it.
Q. This says that a report was prepared on 20 January 2011, and that, "The laboratory studies investigated initially potential improvements of the TEA process, for instance by changing solvent ratios, but this was concluded as not successful because of increased costs and yields still below expectations."
That's correct, right?
A. Let's see. The TEA process. I don't think I recall the TEA process reports.
Okay. Go ahead. I saw it. It lists -- this is right there.
Q. Reading further in now the third paragraph under quality management it states, "Further studies lead to the development of the zinc chloride process by changing solvents and reagents, for example, zinc chloride, DMF."
Do you see that?
A. Yes.

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Q. This states, "Trials on different conditions were performed, and a final recommendation was provided to ZHP Chuannan. The project report did not address the formation of impurities or the change of the impurity profile itself."

Do you see that?

A. I see the statement, yes.

Q. And the failure to address the formation of impurities or the change of the impurity profile was a deviation from good manufacturing practices, right?

A. What was that? You read a statement, or that's a question?

Q. I'm asking you to confirm that the failure by SynCores to address the formation of impurities and the change of the impurity profile were violations of good manufacturing practices at the time, correct?

MR. BALL: Objection. Foundation.

THE WITNESS: Adam, we keep

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asking this question many, many times.

You put this into content. That's back in 2010 and 2011. We did whatever we can. We follow GMP guidelines. We follow the ICH guidelines. We keep the process change. We make sure that we produce better quality, which is approved by EDQM and FDA.

Why are you always coming back with the same question asking me correct or not? Please don't. You're confusing me now.

BY MR. SLATER:

Q. The failure by SynCores to address the formation of impurities and the change of the impurity profile violated good -- current good manufacturing practices at the time, correct?

MR. BALL: Objection.

THE WITNESS: That's not correct. You're looking

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backwards. I'm sick and tired of this question.

BY MR. SLATER:

Q. Looking backwards, right now, you would agree it violated current good manufacturing practices, right?

MR. BALL: Objection.

THE WITNESS: I disagree. Look in the content. Put in the time frame, Adam, please.

BY MR. SLATER:

Q. Let's just go slow. Because I think maybe if you listen to my question, maybe it won't be as contentious. This says -- well, I'm asking you this: The failure by SynCores to address the formation of impurities or the change of the impurity profile, I'm asking, was that a violation of current good manufacturing practices to fail to do those things?

MR. BALL: Objection. Foundation. Vague.

THE WITNESS: Adam, you

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making me confused.

BY MR. SLATER:

Q. I'll try to ask it a little differently.

You would agree with me that current good manufacturing practices required SynCores to address the formation of impurities connected with the change to the zinc chloride DMF process, correct?

A. I don't know what's correct anymore. Because David -- Adam, when we doing things now, we may have to file this to find out it's not right again.

So you're asking me back in 2010, '11, violate the GMP regulation or not, the answer is no, because at that time we follow all the GMP regulations.

Q. Reading further --

MR. SLATER: If you can scroll down a little more, Cheryll, please. Thank you.

BY MR. SLATER:

Q. Reading further down now

underneath the quality management section, it says "D2. Major. As part of the root cause analysis of the NDMA/NDEA contamination, the development of the 2011/2012 revised valsartan manufacturing process (introduction of the zinc chloride process) was reviewed and the following observations were made."

Do you see where I'm reading?

A. Yes. I see what you're reading.

Q. This states under D2-A, "The modified process was developed by the Huahai Pharmaceuticals R&D facility, Shanghai SynCores Technologies, Inc. Contrary to what the company stated in their retrospective analysis of the process change, the core principles of ICH Q8, Q9, and Q10 were not considered and potential impurity profiles and associated risks were not addressed by the R&D laboratory."

You see what I just read,

correct?

A. I read it. But that's a general statement. I would like to be more specific, okay.

Q. Right. So you were just saying a moment ago that you believed that SynCores followed all of the requirements for good manufacturing practices. Based on what I just read to you, that's what the -- that's what was being told to the European authorities back in 2018, and the European authorities disagreed and said that the core principals of ICH Q8, Q9, and 10 were not considered.

Do you see that?

A. I see that. Adam, don't forget, okay, the same process was developed and approved by EDQM, and they would inspect us many times before 2018. If they knew that, okay, why -- why should they approve that? Same as for the FDA.

Q. Are you saying that the

failure by SynCores to identify the potential impurity profile and associated risks with the zinc chloride process is actually the fault of a regulatory authority?

MR. BALL: Objection. Mischaracterizes his testimony. That's not what he said.

THE WITNESS: Adam, I'm really tired of these questions. How many times do you want me to repeat?

You cannot -- you cannot look at things now, okay, and looking back ten years ago, I'm sure there's some things okay now, today, that would be not okay after ten years. So don't confuse me, please.

BY MR. SLATER:

Q. Well, what I'm asking you is this: Are you saying that ZHP's failure to identify potential impurities and associated risks with those impurities

was not the fault of ZHP, but rather the fault of a regulatory agency that didn't identify that ZHP had missed this?

MR. BALL: Objection. Mischaracterizes his testimony.

THE WITNESS: Adam, this is -- I don't know. Next I'm going to count how many times you say that.

It was out of our knowledge at that time. I'm not blaming anybody else, okay. We just don't know. Nobody knows. The industry doesn't know. The FDA doesn't know. The EDQM doesn't know at that time.

BY MR. SLATER:

Q. Without telling me why this happened, just tell me if I'm correct that this did happen and I'm reading right from the document.

"Potential impurity profiles and associated risks were not addressed by SynCores." And I'm talking about

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specific to the use of DMF.
Is that a true statement?
MR. BALL: Hold on. Where are you in the document? I don't even see where you are in the document.
THE WITNESS: Yeah, I don't see it either.
But it's just a general statement.
BY MR. SLATER:
Q. What I'm going to ask you is this: I'm using what's in the bottom of the document, but I'm going to ask you a straight question. I'm not asking you why this happened. That's not my question.
I'm just asking factually, is this true.
SynCores failed to consider the potential impurity profiles and associated risks attendant to the use of DMF in the zinc chloride process.
Is that a true statement?

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A. Adam, that's not true, because like I said, when we do any process optimization or improvement, the first thing we do is a precondition. So we compare impurity profile with original process. That has to be done before we can -- moving forward.
Q. Is there a document that you can point me to that shows somebody at SynCores evaluating the impurity profile for DMF as it would be used in the zinc chloride process? Is there a document that can show me that?
A. For scientific communities you are comparing the detailed analysis of C of A, certificate of analysis. They list each individual impurities in the table. You can go back and compare.
Q. You're telling me if I go back tonight and look for the certificate of analysis file, I'll see one for DMF that will evaluate the potential impurities of DMF or related to DMF in the zinc chloride process?

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A. Adam, you should have gained more knowledge about the pharmaceutical analysis. It may not say specifically to the DMF or zinc chloride. But in the impurity profile, it will compare new, old, different solvent, different catalyst, different temperatures, different everything.
It would compare that. You want to make sure the new process will produce better quality materials.
Q. Will I see a document if I look in the files in connection with the development of this process where somebody evaluated potential impurities with DMF, including decomposition or degradation impurity known as DMA, dimethylamine, will I actually see a document that lists that as something that was considered?
A. Adam, you going back to the other question again.
Adam, for anybody, or do anything, they may not record every --

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each individual details. You're asking too much. You have to know, to learn, how to see the CoA, how to compare impurity profiles.
MR. SLATER: And on that note I think we've reached five hours.
MR. BALL: Five hours and 7 minutes.
(Discussion was held off the stenographic record.)
THE VIDEOGRAPHER: The time right now is 12:57 p.m. We're now off the record.
*****
(Excused.)
(Deposition adjourned at approximately 12:57 p.m. China Standard Time)

CERTIFICATE

I HEREBY CERTIFY that the witness was duly affirmed/sworn by me and that the deposition is a true record of the testimony given by the witness.

It was requested before completion of the deposition that the witness, ERIC GU, Ph.D., have the opportunity to read and sign the deposition transcript.

____
MICHELLE L. GRAY,
A Registered Professional
Reporter, Certified Shorthand
Reporter, Certified Realtime
Reporter and Notary Public
Dated: March 7, 2021

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After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I,______________________, do hereby certify that I have read the foregoing pages, 1 - 282, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

____
ERIC GU, Ph.D. DATE

Subscribed and sworn
to before me this
_____ day of ______________, 20____.
My commission expires:______________

____
Notary Public

LAWYER'S NOTES

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